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84-1620

No.

IN THE

Supreme Court of the United States

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,

v.

CIBA-GEIGY CORPORATION,
Respondent.

PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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Questions Presented

1. Whether petitioner can be enjoined, under the Lanham Act and state law of unfair competition, from selling a generic version of respondent's brand name prescription drug in capsules having the same colors as respondent's capsules after the patent on the active ingredient in respondent's drug has expired.

Subsidiary Questions

2. Whether the colors of respondent's brand name drug capsules can become a trademark (attain "secondary meaning") solely on evidence of promotion to health professionals, commercial success of the brand name product and copying by generic drug manufacturers, without evidence that patients identify color with source.

3. Whether the colors of respondent's prescription drug capsules are non-functional and can become a trademark.

4. Whether the copying of the colors of respondent's brand name drug renders petitioner, a generic drug company, vicariously liable for the activities of druggists who may pass-off the generic drug for a brand name drug.

All questions were answered in the affirmative by the New Jersey District Court in this case, affirmed by the Third Circuit Court of Appeals, following *SK&F Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980).

All questions were answered in the negative by the New York District Court, affirmed by the Second Circuit Court of Appeals on remand from this Court in *Ives Laboratories, Inc.* v. *Darby Drug Co., Inc.*, 488 F.Supp. 394 (E.D.N.Y. 1980), rev'd. 638 F.2d 538 (2d Cir. 1981), rev'd. sub nom., *Inwood* v. *Ives*, 456 U.S. 844 (1982), aff'd. on remand 697 F.2d 291 (2d Cir. 1982). (See the unreported opinion of the Second Circuit. (App. 58)*

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Opinions Below

District Court for the District of New Jersey granting a preliminary injunction. (App. 8-50) 547 F. Supp. 1095 (D.N.J. 1982).

Court of Appeals for the Third Circuit affirming grant of preliminary injunction. (App. 1-4) 719 F.2d 56 (3d Cir. 1983).

Order of District Court converting the preliminary injunction hearing to a trial on the merits. (App. 51-53) Unreported.

Final Judgment and Order of the District Court granting a permanent injunction. (App. 54-55) Unreported.

Court of Appeals for the Third Circuit affirming the District Court's final judgment and order granting a permanent injunction. (App. 61-103) 747 F.2d 844 (3d Cir. 1984).

Jurisdiction

A writ of certiorari is sought to review the judgment of the United States Court of Appeals for the Third Circuit dated and filed November 2, 1984.* The jurisdiction of this Court is invoked under 28 U.S.C. Sections 1254(1) and 2101(c).

Statutes Involved

The federal statutory provision involved is Section 43(a) of the Lanham Act, 15 U.S.C. Section 1125(a). The state statutory provisions involved are New Jersey Statutes Annotated, Sections 56:4-1 and 56:8-2. These provisions are set forth in full in the Appendix at App. 56-57.

Statement of the Case

1. Basis for Federal Jurisdiction

This is an action brought by Ciba-Geigy Corporation (Ciba) against Bolar Pharmaceutical Co., Inc. (Bolar) under section 43(a) of the Lanham Act (15 U.S.C. 1125 (a), App. 57) and New Jersey state law to restrain Bolar

* A petition for rehearing was denied on January 8, 1985. (App. 105)

from duplicating the color of Ciba's Apresazide capsules for Bolar's generic version of the drug. (App. 68) Ciba asserted jurisdiction under 15 U.S.C. § 1121, 28 U.S.C. §§ 1331, 1388 and the doctrine of pendent jurisdiction.

2. The Claims

Ciba claims that Bolar's use of similarly colored capsules for its generic version of the drug first sold by Ciba constitutes false designation of origin and unprivileged imitation. This claim is based on the contention that capsule colors, although unregistered, act as a trademark which indicates the source of the product to consumers, and that capsule colors are non-functional. Ciba also claims that Bolar's use of the same color on its capsules facilitates illegal passing-off of Bolar's product as Ciba's product by unscrupulous pharmacists, and that since Bolar could reasonably anticipate such illegal activity, Bolar is vicariously liable for the pharmacists' illegal acts.

Bolar contends 1) that capsule color does not indicate the source of a prescription drug to a consumer, but is associated in the consumer's mind with the drug (i.e., "my red heart pill") not the source, 2) that capsule colors are functional in that they are important to the use and purpose of drug capsules, and 3) that a manufacturer cannot be liable for the acts of retailers based solely on the manufacturer's activity of copying an unpatented, unregistered aspect of a product, under the applicable standard for vicarious liability recently set out by this Court in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844, 854 (n. 13), 72 L. Ed.2d 606, 615 (1982) (herein referred to as "Ives").

3. The Facts

Ciba, like all brand name companies, spends years and substantial monies in the development and promotion of its products. (App. 9) It invents drugs and establishes markets for them through advertising which is directed to doctors and by "detailing" (salesmen visiting doctors and leaving samples and promotional material). (App. 12) Ciba does not advertise its prescription drugs to consumers. (App. 68) Ciba is granted patent monopolies of varying durations, which depend upon how much of the 17 year patent term has expired when the Food and Drug Administration (FDA) grants permission to sell the new drug. (App. 66-7)

Apresazide, the drug in question, is a combination of a diuretic and vasodilator, taken for relief of hypertension and high blood pressure. (App. 67) The generic names for its active ingredients are hydralazine hydrochloride and hydrochlorothiazide. (App. 67) Ciba's sales director, and Bolar's expert witnesses (a doctor and a pharmacist) testified that the trade name, Apresazide, has become the common descriptive name for the drug because the generic name, hydralazine hydrochloride/hydrochlorothiazide is long and cumbersome (as are most generic names compared to brand names). (R. 73-77, 136, 143, 147, 353-361).* Bolar, of course, must and does use the unwieldy generic name on its labels. (App. 29)

Ciba received FDA approval for Apresazide in 1976 and was the exclusive supplier of the drug until March,

* Record references are to numbered pages of the Record on Appeal, and include documentary exhibits. Physical exhibits are referred to by trial exhibit number.

1982 when its patents were dedicated to the public as a result of an antitrust action brought by the Justice Department. (App. 15) *U.S.* v. *Ciba-Geigy Corporation,* 1976-1 Trade Cases, ¶ 60,908 (D.N.J., 1980). Although Ciba spent more than $25 million in advertising and promotion between 1976 and 1981, such advertising was directed solely to doctors, pharmacists and hospitals. No advertising or promotion was directed to or ever reached consumers of Ciba's product. (App. 68)

Ciba has always sold Apresazide in the same color capsules, blue and white for 25 mg./25 mg., pink and white for 50 mg./50 mg. and pink flesh and white for 100 mg./50 mg. Although the name, Apresazide, is a registered trademark, the capsule colors were not registered by Ciba as a trademark and are not the subject of a design patent. (App. 15) When a brand name company originally chooses a color or color combination for a new product, the choice is arbitrary. At that point the color has no therapeutic effect and is used only to differentiate dosages and sometimes to distinguish one drug from another. This was true of Ciba's product in the case at bar. (App. 15)

Bolar, like other generic drug companies, is authorized to sell a generic version of the brand name drug after the patent on the brand name drug has expired and after the FDA has determined that the generic drug is equivalent to the brand name approved drug. See *U.S.* v. *Generix Drug Co.,* 460 U.S. 453, 103 S.Ct. 1298, 75 L. Ed.2d 198 (1983). Because generic drug companies do not develop new products or markets, and usually do not advertise, their costs are much lower than brand name companies and thus generic companies sell their products more

cheaply. (App. 9) These savings are usually reflected in the lower prices charged by pharmacists to consumers for generic drugs.

Bolar received FDA approval for its version of hydralazine hydrochloride/hydrochlorothiazide in 1982 and began selling the product in the same colored capsules as Ciba's Apresazide. (App. 18)

While the drug is on-patent, the patients who use the drug become accustomed to its appearance. This is particularly true for maintenance drugs (such as Apresazide) which are taken on a regular basis over a long period of time, sometimes for the rest of a patient's life. (App. 9) In this case, as in the *Ives* case and in every drug look-alike case involving maintenance drugs, doctors and pharmacists have testified that patients identify the color of their capsules with the medication itself, not its source; and that patients are initially anxious or confused when their prescriptions are refilled with pills in an unfamiliar color, but they will usually be reassured if a doctor or druggist tells them that the unusual looking pill is a generic equivalent. (App. 9) Doctors have also testified in these cases that patients who take more than one drug each day use color to follow prescription instructions, and color identification of pills can sometimes be useful in emergency situations.* (R. 351, 369, 372, 510-513; See *Ives,* 456 U.S. at 853, 862).

* Based on this identical testimony, the district court in *Ives* found color of drug capsules to be functional, while the New Jersey district courts (including the court in this case) found color non-functional.

Pharmacists receive brand name drugs and generic drugs in large bottles clearly marked with the name of the manufacturer and distributor* (*Ives*, 456 U.S. at 848). They remove the pills from those bulk containers when filling a prescription and place the pills in prescription vials. (App. 68) (*Ives*, 456 U.S. at 848-9) The label on the vial in which the brand name product is placed, states the brand name (e.g., Apresazide) while the label on the vial containing generic capsules states the generic name (hydralazine hydrochloride/hydrochlorothiazide) and the name of the manufacturer or distributor. The patient never sees the original bulk container received by the druggist from the manufacturer or distributor. (*Ives*, 456 U.S. at 848-849)

All states have drug substitution laws giving doctors the option of using the brand name on the prescription pad and directing the druggist to dispense either the brand name drug ("dispense as written") or a generic equivalent ("substitution permitted"). If the doctor directs "substitution permitted", the druggist must dispense the generic drug. (*Ives*, 456 U.S. at 847, fn. 4)

Some pharmacists have taken advantage of the difference in price of generic and brand name drugs by dispensing generic pills when the brand name is called for, putting the brand name on the vial label and charging the higher, brand name price.** This practice is obviously

* Bolar's containers also contained a prominent yellow label cautioning pharmacists to substitute only where permitted by law and only after informing the patient of the substitution. [PX 16-17]

** Although there was no evidence of illegal substitution of the drug in question, the district court took judicial notice of 93 criminal convictions of pharmacists in New York for illegal substitution (none of which involved a Bolar product or Apresazide), and evidence of illegal substitution introduced in other New Jersey drug trademark cases involving other parties and different products. (App. 32, fn. 9)

illegal and can subject the pharmacist to criminal penalties, including fine or imprisonment, as well as loss of his license to practice pharmacy. (New Jersey Statutes §§ 24:6E7, 24:6E-11, New York Education Law §§ 6808, 6809, 6816(1)

It is undisputed, and the district courts in this case as well as in *Ives* so found, that both legal and illegal substitution of generic drugs is facilitated if the generic looks like the brand name drug to which patients have become accustomed. (App. 9, 18; *Ives,* 488 F.Supp. at 398-399)

All drug capsules and tablets, generic and brand name are now universally stamped with the name or logo of the source and an NDC code number. (App. 19)

The only activity charged to Bolar is copying Ciba's capsule colors. There is no evidence of any suggestion by Bolar that its capsules be passed off as Ciba's, nor is there evidence that Bolar sold to a retailer with knowledge that the retailer had engaged in passing-off.

The facts in this case are the same as the facts that were presented to this Court for review in *Ives* and are the same as the facts presented in numerous cases in which brand name drug manufacturers have sought to enjoin generic drug companies from copying the appearance of brand name drugs that are off-patent. Despite the *Ives* decision, where the Court held that the copying of capsule color was permissible, the district courts in New Jersey (affirmed by the Third Circuit Court of Appeals) continue to enjoin generic drug companies from copying the color of brand name drugs.

4. Procedural History

Shortly after filing its complaint Ciba moved for a preliminary injunction. The New Jersey District Court granted Ciba's motion after holding an evidentiary hearing. (App. 5 and 8) The Third Circuit Court of Appeals unanimously affirmed the District Court. (App. 1) Bolar petitioned for a writ of certiorari, which was denied (No. 83-1163).

While the petition for certiorari was pending, the District Court converted the preliminary injunction into a permanent injunction with the consent of the parties. (App. 51) The Third Circuit again affirmed, this time in a 2 to 1 decision with a strong dissent by Judge Giles. (App. 61) The majority termed the dissenting opinion "thoughtful", but was constrained to follow the construction of New Jersey law made by a prior panel in *SK&F Co. v. Premo, supra.* (App. 83, fn. 10) The dissent argued that this Court implicitly overruled that portion of *SK&F* relied on by the majority. (App. 95)

Bolar here seeks a writ of certiorari to appeal the majority decision of the Third Circuit Court of Appeals.

REASONS FOR THE ALLOWANCE OF THE WRIT

I.

The New Jersey District Court Has Established a National Law Against Look-Alike Drugs, In Conflict with the Decisions of this Court and the Second Circuit Court of Appeals.

The New Jersey District Court has become a haven for major pharmaceutical companies seeking to inhibit generic competition after their patents expire. Bolar and other

generic drug companies have been repeatedly sued in New Jersey for the sale of generic drugs in their accustomed color.* By evading the rulings and rationale of this Court's decisions in *Ives, supra,* and *Kellogg Co.* v. *National Biscuit Co.,* 305 U.S. 111 (1938) and by ignoring long established rules concerning secondary meaning and functionality, the New Jersey District Court has effectively established a national law against the manufacture and sale of a generic drug in the only appearance by which the drug is recognized.

The Third Circuit Court of Appeals and the New Jersey District Court continue to find generic drug manufacturers liable for presumed illegal acts of druggists if the manufacturers can reasonably anticipate that the druggists will illegally substitute the generic for a brand name drug. This Court stated in *Ives* that the "reasonable anticipation" standard was improper; nevertheless, the Courts below find reasons to ignore or avoid that ruling. This Court must now act to review the decisions below

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* See American Home Products Corp. v. Chelsea Laboratories, 572 F.Supp. 278 (D.N.J. 1982), aff'd. without opinion, 722 F.2d 730, (3d Cir., Sept. 29, 1983); Biocraft Laboratories, Inc. v. Merck & Co., 532 F.Supp. 1068 (D.N.J. 1980); Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories, 532 F.Supp. 1040 (D.N.J. 1980); SK&F Co. v. Premo Pharmaceutical Laboratories, Inc., 481 F.Supp. 1184 (D.N.J. 1979), aff'd., 625 F.2d 1055 (3d Cir. 1980); Hoffman LaRoche v. Premo Pharmaceutical Laboratories, Inc., 210 U.S.P.Q. 374 (D.N.J. 1980); Merrell-National Laboratories, Inc. v. Zenith Laboratories, Inc., 194 U.S.P.Q. 157 (D.N.J. 1977), aff'd. on procedural grounds, 579 F.2d 786 (3d Cir. 1978). Additionally, numerous other cases have been filed in the District of New Jersey by virtually every brand-name company in order to enjoin the marketing of generic drug products in colors which are similar to their brand-name counterparts. See e.g., Sandoz, Inc. v. Danbury Pharmacal, Inc., 83 Civ. 4771 (D.N.J.) (complaint filed Dec. 12, 1983); Ciba-Geigy Corp. v. Zenith Laboratories, Inc., et al., 82 Civ. 671 (D.N.J.) (complaint filed March 4, 1982).

or accept the disregard of its ruling by the New Jersey District Court and the Third Circuit Court of Appeals.

Similarly, the Courts below disregard the standard for finding "secondary meaning" established by this Court in *Kellogg* and reiterated in *Ives*. The Courts below find trademark significance in drug capsule color without any evidence that patients identify color with the source of the drugs. The New Jersey District Court continues to base its findings of secondary meaning on proof of advertising and sales by brand name companies, and copying by generic companies. This proof is inapposite in the context of pharmaceutical industry. Consequently, the Courts below grant trademark significance to drug capsule colors without any evidence that the colors indicate that their primary significance in the minds of the public is to identify the source of the product rather than the product itself.

The Courts below also conclude that drug capsule colors are non-functional, despite undisputed evidence of their functionality and despite specific factual findings by the District Court itself establishing the functionality of color.

Finally, the Courts below base their decisions upon the public policies in favor of informed patient consent and against illegal substitution, which are goals that can be achieved without enjoining the copying of capsule color. Such injunctions clash with significant public policies of encouraging competition after patents expire, and making available to consumers the useful aspects of non-patented products.

Due to the conflict between the New Jersey District Court's decisions and the rulings of this Court (as well as the Second Circuit)* in *Ives*, a race to the courthouse now determines whether a particular generic drug can be sold in the same colors as its brand name equivalent. If the case is brought in New Jersey by a brand name company, the copying of the colors is prohibited. If a generic company succeeds in bringing a declaratory judgment action in New York, the act of copying the brand name colors is permitted. Review by this Court is necessary to clarify the effect *Ives* has on the controlling precedent in the Third Circuit (*SK&F Co.* v. *Premo, supra*) and to resolve the conflict between the circuits which presently exists. For the reasons stated below, the conflict should be decided in accordance with the rational of this Court's decisions in *Ives*, and in *Kellogg v. National Biscuit Co., supra.*

a. Contributory Trademark Infringement: The Continued Use by the Courts Below of the "Reasonable Anticipation" Standard in Finding Vicarious Liability of a Manufacturer for the Acts of a Retailer, After the Rejection of That Standard in *Ives*.

The most striking departure made by the District Court and the Court of Appeals from the law established by this Court in *Ives* is the retention by the courts below of the "reasonable anticipation" standard for finding vicarious liability of a manufacturer for the passing off of his product by a retailer. Prior to *Ives*, the Third Circuit Court of Appeals held a manufacturer was liable for passing off under the Lanham Act and under New Jersey law if the manu-

* On remand from this Court in *Ives*, the Second Circuit affirmed the district court dismissing all claims of trademark infringement and unfair competition, "substantially for the reasons stated by Judge Nickerson. . . .". App. 58-59.

facturer placed a drug "in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off." *SK&F Co.* v. *Premo, supra,* 625 F.2d at 1062, 1065-1066.

In *Ives,* Justice White, in a concurring opinion, considered whether the Second Circuit properly applied the reasonable anticipation standard to a claim for contributory infringement under the Lanham Act. *Ives,* 456 U.S. 844 at 860, (White, J. concurring). He rejected the reasonable anticipation standard as "watered down" and stated "[t]he mere fact that a generic drug company can anticipate that some illegal substitution will occur to some unspecified extent and by some unknown pharmacists, should not by itself be a predicate for contributory liability." *Id.* 456 U.S. at 861.

The majority in *Ives* responded to Justice White's comments by stating that if the Second Circuit had relied upon the reasonable anticipation standard, "the Court indeed would have applied a 'watered down' and incorrect standard." *Ives,* 456 U.S. at 854, fn. 13. Both the majority and Justice White in *Ives* agreed that a manufacturer could not be held liable for contributory trademark infringement based solely upon evidence of copying, and that evidence of intentional inducement of the pharmacist to pass off, or the knowing continued sale to a pharmacist who was passing off, was required to support a finding of vicarious liability. Nevertheless, the New Jersey District Court continues to use the "reasonable anticipation" standard to find Bolar responsible for assumed acts of pharmacists in this case. (App. 45)

The district court seeks to avoid this Court's rejection of the "reasonable anticipation" standard by pointing to the fact that the contributory infringement claim in *Ives* was brought under section 32 of the Lanham Act while the contributory infringement claim in this case is brought under section 43(a) of the Lanham Act, which prohibits a broader range of practices than does section 32. (App. 46)

While section 43(a) does prohibit more activities than does section 32,* there is no basis in reason or in law to hold that the same activity creates no liability under section 32 but is actionable under section 43(a). The discussion of this issue by Judge Giles in dissent below is informative and persuasive. After discussing the two statutory provisions, Justice Giles concludes:

> "However, the nature of the activity, duplicating a drug's trade dress, and the potential for wrongdoing by an unscrupulous pharmacist, are the same regardless of which statutory section a plaintiff invokes. Consistency and logic dictate, therefore, that the same legal standard should be applied to the same behavior under both sections 32 and 43(a). To hold that a plaintiff need only prove reasonable anticipation under section 43(a) would render section 32 superfluous and eviscerate the intentional inducement standard of Ives. No plaintiff would voluntarily choose to proceed under section 32, given the higher burden under Ives, when they could invoke section 43(a) and be required to prove only reasonable anticipation. Moreover, the Ives court indicated that the standard for functionality is the same under both statutory sections. See 102 S.Ct. at 2190 n.20; id. at 2192-93 (White, J., concurring). It follows

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* § 32 prohibits misuse of a registered trademark. § 43(a) prohibits false advertising generally, including "false designation of origin".

> that the same must be true for 'passing off'. Thus, I would hold that Ives signaled the demise of the reasonable anticipation standard, implicitly overruling that portion of this court's decision in SK&F." (App. 95)

Anticipating that a reviewing court might hold that the reasonable anticipation standard was "watered down" and improper whether applied under section 32 or section 43(a) of the Lanham Act, the District Court attempted to support its conclusion that Bolar is guilty of contributory infringement by making a factual finding that Bolar intentionally induced pharmacists to pass off its product as Ciba's Apresazide. (App. 30-31, 46-47, 80)

In finding that Bolar had the intent to induce illegal substitution, the District Court and the Court of Appeals below relied on evidence of the conviction of 93 pharmacists in New York for illegal substitution. (App. 31, fn. 9, 80-81) There was no evidence that those pharmacists passed off products produced by Bolar and there was no suggestion that the convictions involved substitution of Bolar's products or any generic product for Apresazide. There is no logical connection between those 93 convictions and a factual finding that Bolar had the intent to induce illegal substitution, or intentionally induced such activity. (Giles, J., dissent, App. 96)

Nor does the assumption that illegal substitution exists to some unspecified extent (relied upon by the district court, App. 31, fn. 9) support a conclusion that Bolar intended that its product be used illegally or intentionally induced such use. There is no doubt that Bolar's product would also be used for legal and proper substitution, nor is there doubt that copying the color of Apresazide would

facilitate such legal and proper substitution. The District Court below made such a finding. (App. 9, 18) Something more than simply copying an unpatented and unregistered feature of a product must be shown to establish intent that the product be illegally used, particularly when the product can be used legally and the feature copied facilitates such legal use. (See, *Sony Corp. of Amer.* v. *Universal City Studios,* —— U.S. —— 104 S.Ct. 774, 78 L. Ed.2d 574 (1984), reh. den. 80 L. Ed.2d 148 (1984)

Moreover, it is clear from the *Ives* decision that more is required to prove contributory infringement on the part of a manufacturer than evidence that he intended his product to be passed off. The manufacturer must not only intend that the retailer pass off but must, in addition, do something to induce such illegal activity. In this case there is no evidence whatsoever that Bolar did anything more than copy the appearance of Apresazide for its generic version. There is a total absence of evidence that Bolar did anything to induce pharmacists to engage in illegal activity. Similarily, there is a total lack of evidence that Bolar sold its product to any pharmacist who Bolar knew was engaging in illegal substitution.

However, even if it is assumed that Bolar could be liable merely for the intent to induce illegal substitution, without doing anything to induce that activity, the courts below erred in ignoring the *Ives* ruling. As Judge Giles stated in his dissent:

> "Assuming that Ives punishes merely the intent to induce illegal substitution, the result remains unchanged. Proof of something in addition to the act of copying is required. It is beyond question that

the Ives standard purports to have substantially more bite than the reasonable anticipation test. Under the latter, the act of copying proves the offense. By imitating the trade dress of a drug, it is virtually impossible to fail to anticipate that 'it may be passed off as another product. . . .' SK&F, 625 F.2d at 1062. Thus, to satisfy the higher standard of Ives, it would seem that proof of something more than the act of imitation is required. However, under the district court's analysis, the same quantum of evidence which would satisfy the reasonable anticipation standard would also suffice to prove intentional inducement. Under either, the act of copying would prove the offense.*

* The district court recognized the effect of his ruling that duplication proved the intent to facilitate passing off. He stated 'such an indictment could logically extend to any generic drug manufacturer who produced a look-alike drug.' Ciba, 547 F. Supp. at 1108.

However, the rejection of the reasonable anticipation test by the Ives Court as 'watered down and incorrect . . . .', 102 S.Ct. at 2188 n.13, mandates that something in addition to the act of imitation is required to satisfy the intentional inducement standard. Since there is insufficient evidence to support the district court's finding of intent to induce, I conclude that his finding is clearly erroneous." (App. 97-98)

Nor can the "reasonable anticipation" standard continue to be applied by the federal courts on the grounds that it is the law of the State of New Jersey. As Judge Giles points out in dissent below, the law of the State of New Jersey on this issue seems to follows the federal law, and the "reasonable anticipation" standard is no longer federal law after the decision in *Ives*. (App. 98-100) Even if the New Jersey state courts adopted the "reasonable anticipation" standard independent of federal court

rulings on the subject, the adoption of such a standard (which would prevent the copying of an unpatented, unregistered feature of an article in commerce by a state court) would violate this Court's rulings in the *Sears* and *Compco* cases* where it was held that states may require labeling to avoid consumer confusion as to source, but state law may not prohibit competitors from copying articles in commerce not protected by any federal grant regardless of secondary meaning or likelihood of confusion.

The decisions of the courts below, using the "reasonable anticipation" standard to find contributory trademark liability on a part of a manufacturer for copying the appearance of a competitor's product, should be reviewed as in conflict with this Court's decision in *Ives* that the "reasonable anticipation" standard was watered down and improper. Likewise, the avoidance of the proper standard for contributory infringement by the Courts below, relying on an unsupported finding of intent to induce based on nothing more than copying the appearance of a competitor's product, should be reviewed and rejected.

b. Secondary Meaning: The Courts Below Find Capsule Colors Are Trademarks Without Evidence That Consumers Think of Color as Identifying the Source of the Product.

In order to establish a claim for unprivileged imitation or false designation or origin, Ciba must prove that the color of its Apresazide capsules has acquired secondary meaning and is non-functional. (App. 79)

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* Sears Roebuck & Co. v. Stiffel Co., 376 U.S. 225, 84 S.Ct. 784, 11 L. Ed.2d 661 (1964), Compco Corp. v. Day-Brite Lighting, Inc., 376 U.S. 234, 84 S.Ct. 779, 11 L. Ed.2d 669 (1964).

To establish secondary meaning, "a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself. See *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 118 (1938), 83 L. Ed. 73, 59 S.Ct. 109." *Ives*, 456 U.S. at 851 n.11.

In *Ideal Toy Corp.* v. *Plawner Toy Mfg. Corp.*, 685 F.2d 78, 82 (3rd Cir. 1982) the court below stated:

> "[w]hen the primary significance of the trade dress *to a consumer* is in designating *not the product but its producer*, the trade dress has acquired secondary meaning." (emphasis added)

In cases where the consumer is the target of manufacturer advertising and where the consumer chooses the product being purchased, factors such as the extent of sales and advertising, the length of use and the fact of copying have been held probative of secondary meaning. In finding that Ciba had established secondary meaning in this case, the courts below relied exclusively on these factors. (App. 16-17, 24, 40-42, 73-75, 79-80) There was no direct evidence in this case, or in any of the generic drug color cases decided in New Jersey, of consumer attitude toward the significance of color. Not a single patient testified that the primary significance of color in a drug capsule was to identify the source of the capsule. More significantly, no survey evidence was offered in the court below or in any of the New Jersey cases to indicate that the primary significance of color in the mind of the consumer of drug capsules is an indication of their source.

Reliance upon circumstantial evidence such as advertising, extensive sales, period of exclusive use and copying by competitors is logically inapplicable in the pharmaceutical industry. The reasoning of Judge Nickerson in the district court decision in *Ives,* and the statement of Judge Giles in dissent below, need not be paraphrased:

> Judge Nickerson: "But decisions concerning goods which the seller promotes directly to the consumer cannot indiscriminately be used as authority in a case concerning prescription drugs. Where the advertising and promotion are aimed at the customers who make the choice of which product to buy, they may indeed take a non-functional feature to indicate not merely the product but also the producer. In that case, vast expenditures for advertising may suggest that the advertising was successful in implanting in the minds of the consumer the idea that certain features by which the product is promoted identify its source. But extensive promotion to physicians does not establish that they have passed along to their patients any message as to source. For that reason secondary meaning will perhaps be difficult to establish in those prescription drug cases where the patient never sees the manufacturer's packaging. Here Ives certainly did not establish secondary meaning." *Ives Laboratories, Inc.* v. *Darby Drug Co., Inc.,* 488 F. Supp. 394, 401 (E.D.N.Y. 1980)
>
> Judge Giles: "The promotional techniques necessarily employed by the pharmaceutical industry set it apart from more consumer oriented fields. All promotional efforts are directed at physicians and pharmacists, leaving the ultimate consumer uneducated as to the source of the prescription drug. . . . In the context of the pharmaceutical industry, the *Ideal Toy* factors also become somewhat less meaningful. The amount

> of advertising and promotion, which normally helps to familiarize consumers with a product, is not relevant as it is never seen by the public. Similarly, the volume of sales is not telling where the consumer does not *choose* the particular drug. The continuous use of the trade dress is unimportant unless the public recognizes that only one manufacturer uses that color, shape and size. The act of copying, standing alone, is not sufficient to prove secondary meaning." (App. 86-87)

In the *Ives* case, the plaintiff recognized the weakness of evidence of sales and advertising to establish secondary meaning in the pharmaceutical industry, and there introduced survey evidence to indicate that the consumers of the drug in question identified the color of their medication with the brand name of the drug. *Ives,* 488 F. Supp. at 400. Apparently confident that the courts in New Jersey would rule in their favor, brand name companies such as Ciba do not bother to introduce survey evidence as direct proof of the primary significance of color in the minds of consumers. They rely solely on the inapplicable evidence of sales, advertising and copying.

Even if it were assumed that such evidence can prove that consumers identify the appearance of their medication with the brand name, such identification does not necessarily prove that consumers identify color with source. In the words of Judge Nickerson, quoted by Judge Giles in dissent below:

> "No doubt to physicians and pharmacists the word 'Cyclospasmol' signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaigns, and they play no role in choosing what drug to buy. Nothing in this record suggests that they 'understand by

> the word anything more than a kind of drug to which for one reason or another they [have] become habituated.' *Bayer Co.* v. *United Drug Co.*, 272 F.2d 505, 510 (S.D.N.Y. 1921) (L. Hand J.)
>
> "Such patients as read their prescriptions do not attribute to Cyclospasmol 'any other meaning than [as] an ingredient in a general compound, to which faith and science might impart therapeutic virtue.' *Id.*
>
> "Thus, one cannot infer from the fact that patients recognize the name Cyclospasmol that they appreciate that the drug they receive comes from a single source. If they do not know that the word designates a single source, it follows that a color associated with the name does not signify to them a single source and cannot acquire a secondary meaning." *Ives Laboratories, Inc.* v. *Darby Drug Co., Inc.*, 488 F.Supp. 394, 400 (E.D.N.Y. 1980)

The *Ives* decision by Judge Nickerson challenged the brand name drug companies to perform a survey similar to that performed in *Ives,* and if the survey indicated an association between color and brand name, to ask one further question of the survey respondents, "Is the primary significance of the brand name (Cyclospasmol or Apresazide) to identify the source of the product or to identify the medicine in the capsule?" It must be deemed significant that no brand name drug company has conducted such a survey or asked such a question. No such direct evidence of consumer attitudes towards the color of their medication or the name associated with that color was introduced or offered in the court below. The reliance on circumstantial evidence of sales, advertising and copying, in the context of the pharmaceutical industry, should be rejected as a matter of law as proof of secondary meaning.

There is no evidence that consuming patients link the color of Apresazide, or the name Apresazide, with a single source. The decision of the court below, holding that secondary meaning was established by Ciba, is in conflict with the standard enunciated by this court in *Ives* and *Kellogg* and should be reviewed.

c. Functionality: The Courts Below Ignored Undisputed Evidence Of Functionality And Disregarded Even Their Own Findings In Order To Arrive At The Result That Capsule Color Is Non-Functional.

We have discussed above Ciba's failure to introduce any evidence of secondary meaning, despite which the courts held that secondary meaning was established. With respect to the question of functionality, the courts below ignored undisputed testimony that drug capsule colors are functional, and ruled that the feature of the article is non-functional despite a factual finding that the accustomed appearance of the drug makes it "more saleable, because it makes it easier for both the doctor and the pharmacist to substitute the generic drug". (App. 9) The district court also found that patients will "accept the drug more readily" if it has the accustomed appearance by which it is identified and "may resist such substitution, if does not". (App. 9)

This Court set forth in *Ives* the general test for functionality of a product feature:

> "In general terms, a product feature is functional if it is essential to the use of purpose of the article or it affects the cost or quality of the article. See *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225, 238 (1964)

Kellogg Co. v. *National Biscuit Co.*, 305 U.S. 111, 122 (1938)"

Ives, supra, 456 U.S. 844, 850

Another common definition of functionality was used by the Second Circuit Court of Appeals in *Ives* (601 F.2d at 642-643), quoting *Pagliero* v. *Wallace China Co.*, 198 F.2d 339, 343 (9th Cir. 1952). A particular feature of an article is functional if it "is an important ingredient in the commercial success of the product . . .".

The conclusion of the District Court, affirmed by the Third Circuit Court of Appeals, that drug capsule color is non-functional conflicts with the undisputed evidence of functionality. The evidence of functionality in this case was the same as that presented in *Ives* (456 U.S. 844 at 853 and 862) and in every other drug color case. Patients identify color with therapeutic effect and become anxious if their prescription is filled with pills of an unaccustomed color, color is helpful for patients who comingle medications to differentiate one from another, color is helpful in identifying drugs in emergency situations and color helps avoid confusion and mistakes on the parts of those responsible for dispensing drugs.*

We recognize that in *Ives* the strict "holding" of this Court was that the Court of Appeals could not reverse the District Court's factual findings (one of which was that

* It was also proven below that hospitals (where illegal substitution cannot occur) prefer drugs in their accustomed colors regardless of source to simplify staff training and to minimize dispensing errors and patient anxiety. They will pay a premium for drugs in their accustomed colors approximating Ciba's entire cost of manufacture of Apresazide (R. 1455; DX 111)

drug capsule colors are functional) unless the appellate court determined the trial court's findings to be "clearly erroneous." Here the District Court made a finding of fact that color was non-functional and the Court of Appeals osentsibly applied *Ives* by refusing to reverse because it could *not* find the District Court's factual finding to be clearly erroneous. Ordinarily we would not expect this Court to grant certiorari to review a fact bound issue such as whether the District Court's factual finding was clearly erroneous. (See Justice White's separate opinion in *Ives*, 456 U.S. at 859.) However, there are persuasive grounds for granting the writ in this case because the District Court's own *factual findings* support the conclusion that drug color is functional. Only by applying an improper legal standard for determining functionality to the facts did the District Court conclude color is non-functional. The district court below and in *Ives* made the same factual findings but came to different conclusions because they applied different legal standards to the facts. This Court should review the practice of the New Jersey District Court in applying an improper legal standard for functionality of drug capsule colors.

The New Jersey District Court found color non-functional because 1) it served no therapeutic purpose when selected by Ciba, (App. 35) 2) Bolar was able to make and sell the drug in different colors, (App. 20) 3) patient anxiety is relieved by the explanation of a doctor or pharmacist (App. 21-22) and 4) doctors do not prescribe a particular drug based on its appearance alone (App. 37) None of these tests for functionality are appropriate under the legal standard established by this Court in *Ives*.

Obviously the test for functionality must be applied as of the time the competitor enters the market—not when the feature was selected by Ciba. It was the exclusive use by Ciba over a period of years that caused color to become functional. By analogy, the word aspirin was not generic when chosen by the innovator, but became so over time when the public came to identify the name with the product. Only after years of consistent use of a color with a drug product does the color assume a usefulness in identifying the product for dispensers and patients. It is the use of color at the time Bolar entered the market that is significant, not when Ciba first chose its colors for this product. The Court's application of any standard at the time of initial selection is an error of law.

Whether a generic drug company is able to make and sell a particular product in colors different from the innovator is an improper question and applies a legally improper standard to the facts. Pharmaceutical companies are entitled to compete in different ways. Brand name companies compete by differentiating their products from competitors, and promoting their products to pharmacists as superior to competing products. Generic drug companies compete by promoting their products in catalogs as similar or equivalent to competing products, and charging less for their products. Both forms of doing business are legitimate and necessary. The United States Department of Justice submitted a brief *amicus curiae* to the Second Circuit in the first *Ives* appeal (601 F.2d 631 (1979)), in which it stated:

> "Contrary to appellant's assertion (Br., p. 36), the fact that some generically identical drugs are sold

in different colors does not diminish the public interest in allowing the imitation recognized in the *Kellogg*, *Sears* and *Compco* decisions. Competition takes different forms in the drug industry. As noted in 1972 Senate committee print, brand name manufacturers of drugs compete primarily by color differentiation.[14] For that reason, even when they market identical drugs, they do not use generic descriptions, but adopt distinctive trade names and, of course, different capsule colors.[15] Appellees' form of competition is quite different, but equally legitimate. They seek to equate their products as closely as possible with the efficacy of those of the market leader—including the use of identical capsule colors—and compete on the basis of price.

"Two different forms of competition have distinctly different results. Competition through product differentiation tends to sustain higher prices,[16] while efforts to stress brand equivalency tend to reduce drug costs. For various reasons, including the brand name manufacturers' promotion practices and the fact that physicians who prescribe drugs do not have to pay for them,[17] the attempts by generic drug manufacturers to compete through lower prices have met with only limited success.[18]

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14. Competitive Problems in the Drug Industry, Summary and Analysis of Hearings Before the Senate Subcommittee on Monopolies, 1-24 (1972) at 5.

15. See *id.* at 6.

16. *Id.* at 7, 36-39.

17. *Id.* at 3-4.

18. *Id.* at 6-7.

"The relative lack of success, however, does not make either the generic producers' attempt, or their stress on the equivalence of their products with those of the brand name manufacturers, without more, unlawful.

> See *Smith* v. *Chanel, Inc.*, 402 F.2d 562, 566 (9th Cir. 1968). Indeed, competitors not only have a right to copy another's product, but 'there was a strong public interest in their doing so. . . . But this public interest would be lost if appellants could not tell potential purchasers that appellant's product was the equivalent of appellee's product.' "

If the District Court can find color non-functional by applying the legal test of whether Bolar can make and sell its product in a different color, it is in effect prohibiting Bolar and other generic drug companies from competing in the manner that they choose, i.e., by selling the same product for less money. As this Court noted in *Kellogg Co.* v. *National Biscuit Co., supra,* 305 U.S. at 121 and *William R. Warner & Co.* v. *Eli Lilly & Co.*, 265 U.S. 526, 528, 530, (1924) to share fully in the goodwill of a non-patented, non-registered feature of a product, generic drug companies must be permitted to use the publicly accustomed appearance of that product. Applying a legal standard that color is non-functional because a different color could possibly be used, obviously eviscerates the rights of the competitors firmly established in *Kellogg* and *Warner*.

The District Court's standard that color is non-functional because patient anxiety can be relieved by a doctor's explanation is also improper. It is the need for the explanation, based upon capsule appearance, that makes the appearance functional. It is noteworthy that the District Court below found that explanations are necessary when color is changed from the accustomed to a different color capsule. (App. 22) If color were identified with source, as the District Court apparently found in determining that color acquired secondary meaning, patients would not seek

explanations when the color of their capsules is changed. It is the fact that patients identify color with the medication than engenders the need for an explanation in the first place. They think they are getting a different drug (not the same drug from a different source). The Court's finding that explanations are needed, whether effective or not, is an acknowledgement that color identifies the product, and not the source, in the mind of the consumer.

Finally, the District Court's standard that drug colors are non-functional because doctors do not prescribe drugs solely on the basis of color, is obviously an improper standard. A feature of an article is functional if it is *an* important ingredient in the commercial success of the product. A generic drug company should not have to show that the feature is *the* important ingredient in its commercial success. Obviously more than one feature of a product can be functional at the same time. If the proper standard for finding functionality were that a doctor prescribed the drug solely because of that feature, no aspect of the product would be functional other than the therapeutic effect of the active ingredient. Such a standard for functionality should not be applied in a prescription drug context. Moreover, it is undisputed that even for Ciba, colors function to differentiate one strength from the other. (The District Court recognized this fact but decided it had no legal significance. App. 21, 36)

Every person of average experience knows drug capsule colors are functional if he but contemplates a pill box containing various medications to be taken at different intervals, or contemplates his own reaction if he were given red pills in a bottle labeled aspirin. The only way that a court

could come to the conclusion that drug color is non-functional, is to apply a strained and improper legal standard to the facts with which all are familiar. That is what the District Court, affirmed by the Third Circuit, has done. These decisions should be reviewed by this Court to insure that proper standards are applied to the question of whether drug capsule color is functional.

II.

Public Policy: Policy Considerations Predominate In Favor of Permitting Generic Drugs to Look Like Brand Name Equivalents.

a. The Anti-Competitive Effect of the New Jersey Decisions.

The United States has adopted a fundamental national economic policy in favor of competition. *United States* v. *Philadelphia Nat'l. Bank,* 374 U.S. 321, 372 (1963). That policy is based upon the premise that competition will result in the best allocation of our country's resources, the lowest prices, the highest quality and the greatest extent of material progress consistent with the preservation of our political and social institutions. *Northern Pacific Railway Company* v. *United States,* 356 U.S. 1, 4 (1958).

One of the most effective ways to compete in a free economy is to copy the unpatented goods of a competitor.

> '[I]mitation is the life blood of competition. It is the unimpeded availability of substantially equivalent units that permits the normal operation of supply and demand to yield the fair price society must pay for a given commodity. . . . Unless such duplication is permitted, competition may be unduly cur-

tailed with the possible resultant development of undesirable monopolistic conditions.'

American Safety Table Co. v. *Schreiber*, 269 F. 2d 255 at 272 (2d Cir. 1959)

The Justice Department's *amicus* brief, submitted to the Second Circuit in the first *Ives* appeal (601 F.2d 631 (1979)), contained the following statement concerning the importance to competition of permitting generic drugs to copy the apperance of brand name equivalents.

"The issue of freedom to compete by copying unpatented articles is especially important in the prescription drug field. Markets for particular prescription drug products are often dominated by major 'brand name' drug companies that have gained their dominant positions through exclusive marketing of the products under patents. *See, e.g., Smith Kline Corp.* v. *Eli Lilly & Co.*, 575 F.2d 1056, 1059-1061, 1065 (3rd Cir. 1978). Once a patent expires, the patent laws envision free and open competition in the product. When the competitive market conditions contemplated by the patent laws for the post-expiration period fail to materialize, society incurs a cost; as a result of successful brand differentiation the established firm often maintains a dominant market share even though its competitors offer the same product at a substantially lower price. (footnote omitted)

"Colored capsules are an important marketing tool in the post-patent expiration period. As a result of the exclusive sale of a patented drug in a particular colored capsule during the lengthy patent period, customers may identify the colored capsule with the therapeutic action of the product. A prohibition of copying the colors of such capsules would tend to perpetuate the market power conferred by the ex-

pired patent and create an artificial and unnecessary barrier to entry and succesful competition in the sale of the particular drugs.

"Patents on numerous important prescription drugs have recently expired or will expire in the next years. J. H. Goldberg, 'MAC's Impact: What's Really Ahead for the Drug Field?' Drug Topics, Dec. 1, 1975. The decision in this case will therefore have a significant impact on the state of competition and prices in the prescription drug field. The United States seeks to asure that no artificial barriers to competition are constructed and that the public obtains the intended benefits of free competition in the post-patent expiration period."

It is the artificial barrier to competition, erected by the New Jersey District Court in confict with this Court's decisions and without basis in the established law of trademarks and unfair competition, that should be reviewed.

b. The Policy Favoring the Use of Generic Drugs.

Virtually every state has expressed its public policy in favor of free competition between generic drugs and off-patent brand name drugs by passing laws encouraging legal generic substitution. *Ives,* 456 U.S. at 847, fn. 4. Because the brand names have become the common names for most prescription drug products, these substitution laws permit generic drugs to be dispensed even when the doctor writes the brand name on his prescription pad, provided he signs the line marked "substitution permitted". Court action, which inhibits this national public policy in favor of free competition between generics and brand names in the prescription drug market, should not be lightly taken.

The obvious advantages to the public in permitting drugs having the same active ingredients and the same therapeutic effect to also have the same appearance, has already been noted. If the standard industry practice which prevailed prior to *SK&F* v. *Premo, supra,* of having equivalent products in similar colored capsules (and tablets), is prohibited by the New Jersey District Court, the patients who use prescription drugs will be deprived of a useful aspect of the product. Having equivalent medication in similar capsules or tablets helps avoid confusion or mistake in dispensing drugs in hospitals and pharmacies, helps patients taking different drugs to follow prescription instructions, may be useful in emergencies, and avoids the feeling of anxiety and distress engendered in a patient who expected blue and white capsules but got a different looking product.

c. The Policies of Informed Patient Consent and Eliminating Illegal Substitution.

The New Jersey District Court bases its decisions against look-alike generic products on two public policy considerations it deems paramount. One is informing the patient who may not know it that generic medication is made by a different company than his previously taken, brand name medication. The other is the desire to minimize or eliminate illegal substitution by some unscrupulous pharmacists. While no one can quarrel with the desirability of promoting these policies, it is wrong to do so by prohibiting the legal and useful copying of an unpatented, unregistered aspect of a product. It is particularly wrong to promote these policies by injunctions against copying when the injunctions conflict with equally important (or more important) public policies of free competition for

unpatented products and the specific encouragement of substitution of generic drugs for unpatented brand name products.* Moreover, the policies of informed consent and minimizing illegal substitution can be achieved without draconian injunctions against look-alike generics.

Illegal substitution could be virtually eliminated by drug companies in a short time, if they choose to devote resources to that cause rather than litigate against competitors in the look-alike cases. In *Ives,* in the 93 New York indictments and in the New Jersey cases cited by the District Court where illegal substitution was shown to exist (App. 31, fn. 9), a simple method of uncovering the illegal activity was proven effective: test shopping. If brand name companies occasionally tested for illegal substitution and turned the results over to state prosecutors or licensing authorities, even unscrupulous druggists would cease the practice. Moreover, illegal substitution is a crime, and can be dealt with by state and local police or prosecuting attorneys. (See e.g., N.Y. Education §§ 6808, 6809, 6816(1); New Jersey statutes § 24:6E-7, 6E-11)

It is also significant that no evidence of illegal substitution was introduced in this case, and the extent of the

* This Court and various circuit courts have favored labeling rather than injunctions against copying to prevent unfair competition through deception as to source. Where an item is labelled as clearly as reasonably possible, the public is free to copy any aspect of the item which is not the subject of a valid patent or registered trademark. *Wm. R. Warner & Co.* v. *Eli Lilly & Co.,* 265 U.S. 526 (1924), *Sears Roebuck & Co.* v. *Stiffel Co., supra, Compco Corp.* v. *Day-Brite Lighting Inc., supra, Bose Corp.* v. *Linear Design Labs, Inc.,* 467 F.2d 304 (2d Cir. 1972), *American Rolex Watch Corp.* v. *Ricoh Time Corp.,* 491 F.2d 877 (2d Cir. 1974), *Smith* v. *Chanel Inc.,* 402 F.2d 562 (9th Cir. 1968)

practice has never been proven or documented. In *Ives* where testing shopping evidence was considered, the court found the practice relatively insignificant. (*Ives,* 488 F. Supp. at 397) Trying to stop illegal substitution by prohibiting copying of unpatented, unregistered features of a product is like trying to kill a fly with a shotgun.

A patient's right to be informed about the medication he takes is well protected without prohibiting copying. The lower price of the generic, the different prescription vial label,* the printing on the capsule and the likelihood that a patient's doctor or pharmacist will mention that he is prescribing or dispensing generically, all satisfy the desire for informed consent without an injunction against copying a useful feature of the article.

The District Court criticizes Bolar's position that look-alike drugs will reduce patient anxiety, arguing that Bolar thus admits that patients are misinformed about the source of their product. (App. 19, 21) This is a misunderstanding of Bolar's position. Look-alike generic capsules do not tell the patient that they come from the same source as the brand name capsules. The color of the capsules is not an indication of source to the patient, but an indication of what drug is inside. A look-alike capsule correctly tells the patient that the same drug is inside—thus relieving anxiety about a mistake or a change in the medication. Because color is not related to source, it cannot inform or misinform a patient about source.

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* If a pharmacist does not use the generic name on the label, but uses the brand name instead, the practice is illegal and can be policed as noted above, without prohibiting copying. If the pharmacist uses the brand name with a notation that it is a generic version (e.g., "Apresazide—Generic") the patient is not misinformed; in fact, the pharmacist is doing exactly what drug substitution laws allow a doctor to do with a prescription pad, use the brand name but indicate a generic version should be dispensed.

Of course, a patient who questions his doctor or pharmacist as to whether the correct medication was dispensed may get an answer about source. (E.g., "It is the same drug, but made by a generic drug company.") While this is useful information, it is not the only way to convey it to the patient and does not warrant the stretching of the trademark law to inhibit competition by prohibiting the useful copying of the capsule color of a drug product off-patent.

The courts in New Jersey seem to be deciding these cases based upon their opinions of what they deem best for the brand name pharmaceutical industry rather than applying established law to virtually undisputed facts.*

* As one European commentator noted about the New Jersey decisions prior to *Ives*:

> "Perhaps one's expectations must necessarily be limited, but the level of analysis in the recent colour get-up judgments has fallen extraordinarily low. The courts seem to be indulging in non-sequiturs, fits of pique, and bizarre overreactions, instead of making measured, rational, dispassionate responses to whatever problems there are in resolving these business conflicts. Moreover, the distribution of what seems to be error and mistake is now quite unrandom; there had been a definite tilt in favour of the brand name drug companies, against the generic sellers. One would not think this to be one of the great political issues of the times; that distorts perception and judicial impartiality. Yet the courts seem to be reacting to generic sellers as if they were trying to subvert Government. Why the courts are doing so seems inexplicable in terms of ordinary common law legal analysis methods based on the categories of trade mark and unfair competition law as they have been developed in regard to other products. Something may be going on in these cases that is not reflected in lines of the courts' published opinions. To predict these judgments is now simple, for the same side always wins. To understand the judgments, perhaps, use of a different discipline is required."
>
> R.H. Stern, "The Persantine, Librax & Elavil Decisions: Colourful Brands of Drugs", 2 European Intellectual Property Review 59 (1981)

The facts of this case, the *Ives* case and the other drug look alike cases are basically the same, only the decisions of the judges in New Jersey and in New York are different. It appears that outcomes depend upon whether the interests of brand name pharmaceutical companies residing in New Jersey are considered to be paramount. If so, findings of fact based on presumptions, not based on evidence are made, such as finding contributory trademark infringement without evidence of suggesting illegal substitution to pharmacists or selling to a pharmacist with knowledge that he engaged in such activity—or finding secondary meaning without evidence that the consumer identifies color with source. The New Jersey courts have ignored legal standards as well as public policy recognized and established by this Court. The public is entitled to the benefits of free competition in all useful aspects of a product after its patent expires. In the market for prescription drugs, this competition also serves the significant policies of lowering the cost of health care.

Conclusion

The New Jersey District Court and the Third Circuit Court of Appeals have created a national policy for the pharmaceutical industry which conflicts with public policies favoring free competition and the public's right to enjoy useful aspects of products after their patents expire. The decisions below also conflict with the law of trademarks and unfair competition as expressed in *William R. Warner Co., Kellogg Co., Sears/Compco* and *Ives*. The decisions below should be reviewed to prevent their anti-competitive

effects from being imposed upon the nation, and to resolve the conflict between those decisions and the decision of this Court and the Second Circuit Court of Appeals in *Ives*.

Dated: New York, NY
April 5, 1985

Respectfully submitted,

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APPENDICES

In The

Supreme Court of the United States

October Term, 1983

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

APPENDIX TO THE PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

No. 82-5797

CIBA-GEIGY CORPORATION,

Appellee

v.

BOLAR PHARMACEUTICAL CO., INC.,

Appellant

Appeal from the United States District Court
for the District of New Jersey
(D.C. Civil No. 82-00788)

ARGUED JUNE 16, 1983

Before: HUNTER and HIGGINBOTHAM,
Circuit Judges, and GILES,*
District Judge.

(Opinion Filed October 14, 1983)

---

* Honorable James T. Giles, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

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OPINION OF THE COURT

Per Curiam

CIBA-GEIGY Corporation ("Ciba") initiated this action on March 12, 1982, alleging that Bolar Pharmaceutical Co., Inc. ("Bolar") had violated Section 43(a) of the Lanham Trade-Mark Act, 15 U.S.C. § 1125(a) (1976) and two independent torts under New Jersey Law, "unprivileged imitation" and "passing off," by copying the trade dress of Ciba's APRESAZIDE products.

Following a lengthy hearing, the district court, relying primarily on *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), granted preliminary injunctive relief. The injunctive relief prevented Bolar from "using any simulation, imitation or substantial duplication of [Ciba's] distinctive trade dress . . . in connection with . . . [Bolar's] hydrolazine hydrochloride/hydrochlorothiazide products for the treatment of hypertension." IV Appendix (App.) 727. The district court based its grant of injunctive relief on its belief (1) that Ciba "demonstrate[d] a likelihood of ultimate success as to at least one of the [counts—either the Lanham-Act count of the State unfair-competition counts]; (2) that Ciba "is threatened with irreparable injury absent such relief;" and (3) "that the balance of equities and the public interest favor such relief." IV App. at 709. Appellant Bolar argues that the district court abused its discretion and made various errors in its findings of fact and conclusions of law. But, we find no merit to appellant's arguments seeking to overturn the grant of a preliminary injunction.

The narrow scope of review of a district court's grant of an application for preliminary injunctive relief permits us to dissolve an injunction only if

> the trial court abuses [its] discretion, commits an obvious error in applying the law, or makes a serious mistake in considering the proof . . . .

SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d at 1066, quoting *A.O. Smith Corp. v. FTC*, 530 F.2d 515, 525 (3d Cir. 1976). See *Scooper Dooper, Inc. v. Kraftco Corp.*, 460 F.2d 1204 (3d Cir. 1972). Thus, an appellant who is attempting to overturn a district court order granting (or denying) a preliminary injunction carries a heavy burden. *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d at 1066; *See, Oburn v. Shapp*, 521 F.2d 142, 147 (3d Cir. 1975); *Scooper Dooper, Inc. v. Kraftco Corp.*, 460 F.2d at 1205.

After reviewing the record, the briefs and arguments of the parties, and Judge Sarokin's thoughtful and detailed opinion, we hold that the district court did not abuse its discretion, commit an obvious error in applying the law,[1] or make a serious mistake in considering the proof.

Accordingly, we will affirm the district court's grant of a preliminary injunction.

---

[1] Appellant also argues that the district court erred in failing to read Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc., ("Ives"), ... U.S. ....., 102 S.Ct. 2182, 2230 (1982), as overruling the reasonable anticipation standard in SK&F Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055 (3d Cir. 1980) for the tort of "passing off" under § 43(a) of the Lanham Act. However, we need not address this issue because the district court's conclusions regarding the New Jersey state law claims of "passing off" and "unprivileged imitation" are mandated by *SK&F* and provide a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief.

A true Copy:

Teste:

Clerk of the United States Court of Appeals for the Third Circuit

App. 5

Filed October 4, 1982

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

Civil Action No. 82-788

ORDER

This matter having been opened to the court by Pitney, Hardin, Kipp & Szuch (Frederick L. Whitmer, Esq. appearing) and by Kaye, Scholar, Fierman, Hays & Handler (Randolph S. Sherman, Esq. appearing), attorneys for plaintiff CIBA-GEIGY Corporation ("CIBA-GEIGY"), and in the presence of Bendit, Weinstock & Sharbaugh (James F. Keegan, Esq. appearing) and Fitch, Even, Tabin, Flannery & Welsh (Robert B. Jones, Esq. appearing), attorneys for defendant Bolar Pharmaceutical Co., Inc. ("Bolar"), and the court having held meetings on April 22, May 12, and June 15, 1982 on plaintiff's motion for preliminary injunction, and the court having heard and considered the evidence and the arguments of counsel, and for the reasons set forth in the Opinion filed by the court on August 11, 1982, and good cause appearing;

It is on this 4 day of October 1982,

ORDERED that CIBA-GEIGY's motion for preliminary injunction be granted, and

A. IT IS FURTHER ORDERED that for the purpose of this preliminary injunction and pending final adjudication, the plaintiff's trade dress for its Apresazide products is described as size 3 capsules having a blue and white opaque color combination, size 2 capsules having a pink and white opaque color combination, and size 1 capsules having a pink flesh and white opaque color combination. Attached hereto and made a part hereof is a photograph, designated Exhibit A, showing the respective colors and shapes (but not the sizes) of the capsules.

B. IT IS FURTHER ORDERED that Bolar Pharmaceutical Co., its officers, directors, agents, employees, servants, attorneys, and all those in active concert or participation with any of the foregoing who receive actual notice of this Order by personal service or otherwise, are hereby preliminarily enjoined, from in any manner, directly or indirectly,

(1) using any simulation, imitation or substantial duplication of plaintiff's distinctive trade dress as described in paragraph (A) of this order in connection with promoting, advertising, selling, offering for sale, marketing, distributing or otherwise placing in the channels of trade any hydrolazine hydrochloride/hydrochlorothiazide products for the treatment of hypertension.

and

C. IT IS FURTHER ORDERED that defendant shall serve a copy of this Order upon all wholesalers, distributors, jobbers, pharmacists and others to whom said product has been sold by defendant or by those in active concert or participation with defendant.

/s/ H.Lee Sarokin
U.S.D.J.

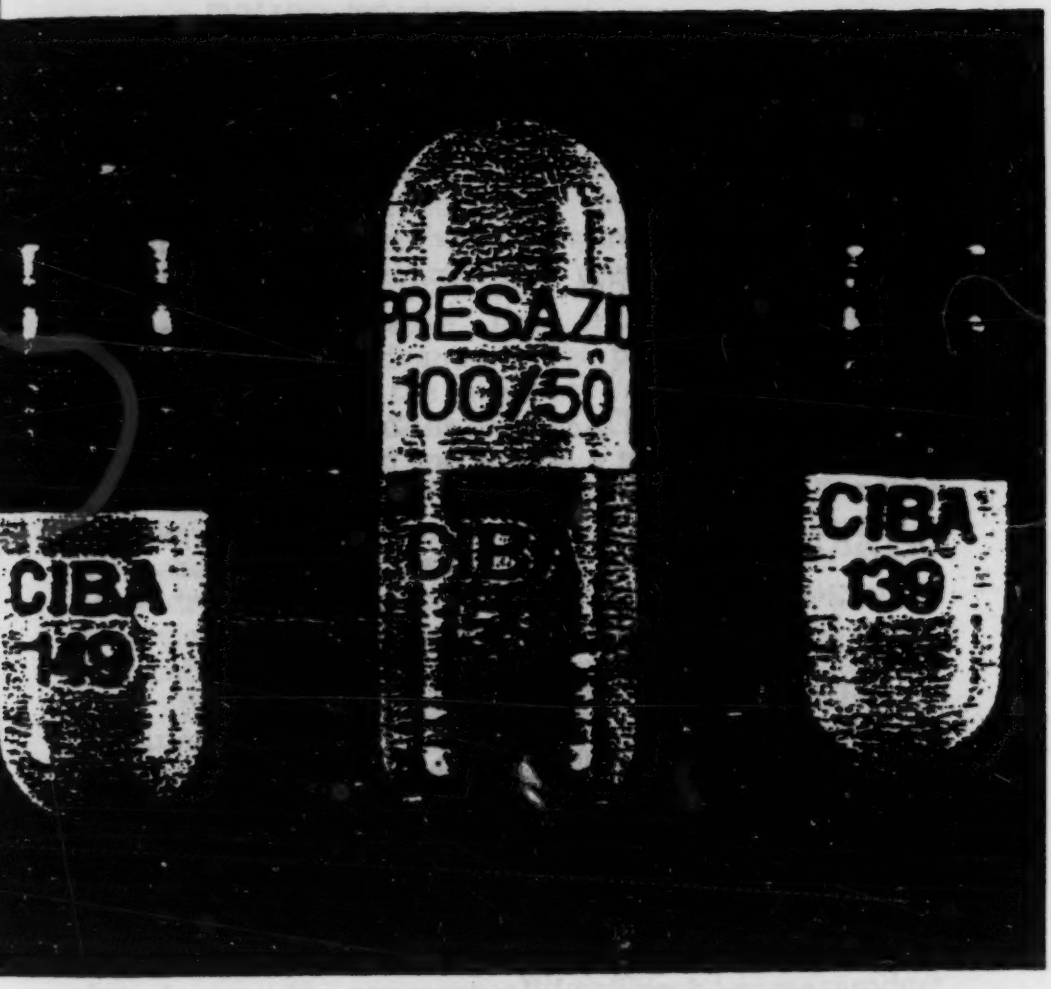

EXHIBIT A

BEST AVAILABLE COPY

Filed August 11, 1982

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

Civil Action No. 82-788

OPINION

SAROKIN, *District Judge*

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INTRODUCTION

Although the battle over "look-alike" drugs raises difficult legal issues, the realities of these repeated skirmishes should not be ignored. The brand name companies have spent years and substantial monies in developing and promoting their product. They not only create the drug but establish a market for it. By virtue of their advertising campaigns, doctors become aware of the drug and its benefits and are encouraged to prescribe it.

The generic "look-alike" drug enters the marketplace with a substantial advantage. The predecessor manufacturer has performed the necessary research and development and has created the market. Therefore, the generic drug can be produced and sold at a much lower cost. The "look-alike" drug becomes more saleable, because it makes it easier for both the doctor and pharmacist to substitute the generic drug. A patient who has utilized the brand name drug over a period of time may accept the generic drug more readily if it looks the same as the brand name. The patient may resist such substitution, if it does not. Most often that anxiety can be dispelled by a simple explanation by the physician or pharmacist regarding the substitution of a generic drug with a different appearance.

On the other hand, the brand name manufacturer contends that the identity of appearance facilitates negligent and intentional substitution without authorization from either the doctor or the patient. To permit the generic drug to copy the appearance of the brand name product increases sales by the generic manufacturer and erodes those of the brand name manufacturer. Although both seek to rest their cause on the public good, it is profit and the desire to earn it which is at the core of this dispute. The generic manufacturer wishes to benefit from the efforts and expense of the brand name manufacturer. The latter wishes to prevent and prohibit such intrusion and retain the benefits for itself.

With this general introduction the court will consider the specific factual and legal issues presented by this matter.

PROCEDURAL HISTORY

Plaintiff CIBA-GEIGY Corporation ("CIBA-GEIGY") commenced this action on March 12, 1982, alleging that defendant Bolar Pharmaceutical Co., Inc. ("Bolar") had violated both the federal and state law of unfair competition by intentionally duplicating the physical appearance (i.e., trade dress) of CIBA-GEIGY's brand name prescription drug APRESAZIDE.® On March 17, 1982, following notice to Bolar, the defendant was temporarily restrained from selling its generic versions of the products in suit in trade dress confusingly similar to that of CIBA-GEIGY's APRESAZIDE products and Bolar was ordered to show cause on March 22, 1982, why such conduct should not be preliminarily enjoined.

Bolar then moved to dismiss the complaint for lack of personal jurisdiction and improper venue. On March 22, 1982, in order to permit development of the jurisdictional facts relative to Bolar's New Jersey contacts and to enable both parties to conduct discovery attendant to CIBA-GEIGY's preliminary injunction motion, the court adjourned the hearing until April 22, 1982 and, with Bolar's consent, continued the temporary restraining order until that date. On April 21, 1982, Bolar advised the court that it was withdrawing its motions.[1]

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[1] CIBA-GEIGY seeks its costs, including attorney's fees, for defending against Bolar's motions on the ground that they were baseless when made and interposed solely for purposes of vexation. Consideration of that application has been deferred pending resolution of the preliminary injunction motion.

Evidence with respect to the preliminary injunction motion was taken on April 22, May 12 and June 15, 1982.[2] CIBA-GEIGY called three witnesses as part of its affirmative case and two rebuttal witnesses; in addition, plaintiff introduced numerous exhibits into evidence, including designated portions of two depositions. Bolar called three witnesses as part of its defense and introduced numerous exhibits into evidence. As to all exhibits accepted into evidence, the court reserved ruling on relevancy objections pending review of the parties' post-hearing submissions, and repeatedly observed that its determination would be based only upon relevant and material evidence.[3]

The temporary restraining order was continued through the May 12 hearing upon Bolar's consent. Thereafter, upon good cause shown, the court continued the order over Bolar's objection.

The following findings of fact and conclusions of law are based upon a careful review of the entire record, an appraisal of the witnesses' credibility and demeanor and the reasonable inferences to be drawn therefrom, the proposed findings of fact submitted by both parties.

FINDINGS OF FACT

A. *The Parties*

CIBA-GEIGY, a New York corporation with a principal place of business in Summit, New Jersey, is engaged, among other things, in the research, development, manufacturer and sale of prescription pharmaceutical products, and in particular the research and development of new prescription drugs for the treatment of hypertension (commonly referred to as high blood pressure). CIBA-GEIGY

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[2] Neither party consented under Rule 65(a)(2) of the Federal Rules of Civil Procedure to advance and consolidate the trial on the merits with the hearing on CIBA-GEIGY's preliminary injunction.

[3] The opinion of the court conforms to that understanding.

devoted a significant portion of its annual research and development budget to research specifically directed at the treatment of hypertension.

CIBA-GEIGY markets brand name pharmaceutical products through two separate divisions, the CIBA Pharmaceutical Company and GEIGY Pharmaceuticals, each having responsibility for the marketing and sale of its own product line. The CIBA Pharmaceutical Company currently markets approximately forty-one prescription pharmaceuticals, ten of which are prescribed for the treatment of hypertension (*i.e.*, anti-hypertensives). The promotion of these products is carried on throughout the United States through a network of some 400 CIBA sales representatives, thirty eight district sales managers, and six regional sales managers. The sales representatives, also known as detail men, personally call upon physicians, retail pharmacists and hospital pharmacies to promote the CIBA line of products through the use of written brochures, reminder or "leave" items (such as pens, rulers and scratch pads) and free drug samples. CIBA-GEIGY does not generally advertise its prescription products directly to the consumer.

Bolar, a New York corporation with its principal place of business in Copiague, New York, is what is known in the pharmaceutical industry as a generic drug manufacturer; that is, it makes and markets under generic names, prescription pharmaceuticals which duplicate the active ingredients of products already researched, developed and sold under brand name by companies such as CIBA-GEIGY. Because their research, development and clinical expenses are generally much less than those of brand name companies, generic drug manufacturers are usually able to sell their products at prices lower than their brand name counterparts.[4]

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[4] In the case of the product in suit, Bolar and CIBA-GEIGY each obtained approval from the Food and Drug Administration by the same Abbreviated Drug Application (ANDA) Procedure [21 C.F.R. 314.1(f)].

Bolar markets its generic pharmaceuticals directly to approximately 400 active customers throughout the United States. These customers are comprised of private label distributors, drug wholesalers and distributors, and federal government agencies. Bolar does not sell its product directly to retail pharmacies; rather, pharmacies purchase Bolar's products through drug wholesalers and distributors which, in turn, buy directly from Bolar. Nor does Bolar promote its generic products directly to physicians and pharmacists, as does CIBA-GEIGY. It is primarily the promotional effort by brand name companies which creates the demand for new prescription drugs.

B. *CIBA-GEIGY's APRESAZIDE Products*

In 1959, CIBA-GEIGY, with the approval of the Food and Drug Administration ("FDA") began manufacturing and selling a combination prescription drug under the registered trademark APRESOLINE-ESIDRIX for the treatment of hypertension. CIBA-GEIGY's APRESOLINE-ESIDRIX product, which it makes and markets in orange, dry-coated tablets, contains two active ingredients: hydralazine hydrochloride and hydrochlorothiazide, in a fixed ratio of 25 mg. to 15 mg. per tablet.

Two factors often responsible for hypertension are vasoconstriction (i.e., constriction of the blood vessels) and excessive fluid volume. Hydrochlorothiazide is a diuretic which reduces excess sodium and fluid volume. However, because hydrochlorothiazide basically treats only the excessive fluid problem, it often proves therapeutically inadequate once hypertension has progressed beyond its milder forms. Hydralazine hydrochloride is a vasodilator which treats vasoconstriction by directly relaxing and dilating arterioles, thereby decreasing peripheral resistance. By combining hydralazine hydrochloride and hydrochlorothiazide, both factors can be treated in a single product. In obtaining FDA approval to market its APRESOLINE-ESIDRIX product, CIBA-GEIGY became the first drug manufacturer to establish the safety and efficacy

of a fixed combination of hydralazine hydrochloride and hydrochlorothiazide for the treatment of hypertension. Subsequent to CIBA-GEIGY's introduction of its APRESOLINE-ESIDRIX product, other drug companies, including Bolar, began selling a combination of 25 mg. of hydralazine hydrochloride and 15 mg. of hydrochlorothiazide in tablet form.

In 1974, faced with the possible market withdrawal or decreased sales of its leading anti-hypertensive product SER-AP-Es, due to an alleged link between one of its active ingredients, reserpine, and breast cancer, CIBA-GEIGY determined that hydralazine hydrochloride, alone and in combination with hydrochlorothiazide, offered the company "the greatest promotional opportunity in a non-reserpine antihypertensive market." In the fall of 1974 CIBA-GEIGY commenced developmental efforts ultimately to bring to market dosage strengths of hydralazine hydrochloride and hydrochlorothiazide in fixed combination ratios of 25 mg./25 mg., 50 mg./50 mg. and 100 mg./50 mg.

In September 1974, CIBA-GEIGY determined, for marketing reasons, that these new combination ratios of hydralazine hydrochloride and hydrochlorothiazide should be made and sold in capsule rather than tablet form. The selection of these products' trade dress was made in order to distinguish the new products from CIBA's other hydralazine-containing products then on the market, all of which, including the APRESOLINE-ESIDRIX product, were being sold in tablet form. There was no medical, pharmaceutical or manufacturing reason which compelled CIBA-GEIGY to make the new combinations in capsule rather than tablet form.

CIBA-GEIGY also selected the capsule color for its new hydralazine hydrochloride/hydrochlorothiazide formulations in September 1974. The initial recommendations were made by Mr. John S. Marmaras, CIBA Pharmaceutical's Design Director at the time. Mr. Marmaras chose color combinations which were "pleasing" to his eye, and then

recommended them to CIBA's Marketing Department for Mr. Barnes' ultimate approval. Two criteria were used in making the ultimate selection: first, the capsule colors should not duplicate those of any other currently marketed major pharmaceutical product; and, second, they should not be displeasing to the eye. The capsule colors which were selected were those in which CIBA-GEIGY eventually marketed its new hydralazine hydrochloride/hydrochlorothiazide combinations under the brand name APRESAZIDE: (a) blue and white opaque combination capsules containing 25 mg. of hydralazine hydrochloride and 25 mg. of hydrochlorothiazide; (b) pink and white opaque capsules containing 50 mg. of hydralazine hydrochloride and 50 mg. of hydrochlorothiazide; and (c) pink flesh and white opaque capsules containing 100 mg. of hydralazine hydrochloride and 50 mg. of hydrochlorothiazide. As in the case of capsule selection, CIBA-GEIGY arbitrarily selected these color combinations based solely on marketing considerations; there was no medical, pharmaceutical or manufacturing reason which compelled the selection of these particular capsule colors.

On May 26, 1976, CIBA-GEIGY obtained FDA approval in the form of an approved Abbreviated New Drug Application ("ANDA") to market its new hydralazine hydrochloride/hydrochlorothiazide combinations. Thereafter, in October 1976, CIBA-GEIGY began to sell these combination products under the brand name APRESAZIDE for the treatment of hypertension. On February 15, 1977, CIBA-GEIGY was granted a federal registration for the trademark APRESAZIDE; and on March 9, 1982, CIBA-GEIGY filed a declaration under Sections 8 and 15 of the Lanham Act (15 U.S.C. §§ 1058, 1065) with the Commissioner of Patents and Trademarks.

Since October 1976, CIBA-GEIGY has continuously marketed its APRESAZIDE products in the same trade dress, and for over five years, from October 1976 to March 1982, it was the sole pharmaceutical company which

marketed these combination products in the particular trade dress described.[5]

From October 1976 to date, CIBA-GEIGY, through its CIBA Pharmaceutical Company division, has spent and continues to spend substantial sums of money advertising and promoting its APRESAZIDE products to physicians, pharmacists and hospitals. During the period October 1976 through 1981, CIBA-GEIGY's expenditures for the distribution of free samples and for promotional and medical literature, films, symposia and seminars promoting its APRESAZIDE products were in excess of $9 million. In addition, during this same period, the cost attributable to the efforts of the CIBA Pharmaceutical Company sales force in promoting APRESAZIDE products was over $16 million.

Since October 1976, CIBA-GEIGY's promotional literature for its APRESAZIDE products, including detailing folders and reminder or "leave" items, has routinely featured the capsules' physical appearance in pictures as well as described them in words. In addition, CIBA-GEIGY has promoted its APRESAZIDE products by distributing free sample capsules to physicians.

CIBA-GEIGY's sales of these combinations have increased steadily and substantially since their market introduction in October 1976. From that time through 1981, CIBA-GEIGY's total annual dollar sales of its APRESAZIDE products increased as follows:

1976 (Oct. - Dec.)	$ 1.1 million
1977	$ 3.4 million
1978	$ 5.3 million
1979	$ 8.3 million
1980	$11.2 million
1981	$14.3 million

[5] Until February 1982, CIBA-GEIGY was the only pharmaceutical manufacturer with FDA approval to market these particular combinations of hydralazine hydrochloride/hydrochlorothiazide at all, regardless of trade dress.

CIBA-GEIGY projects that in 1982 its APRESAZIDE sales will rise to approximately $17 million.

Similarly, from October 1976 through 1981, CIBA-GEIGY's annual APRESAZIDE sales in terms of capsules increased as follows:

	Blue & White 25 mg./25 mg.	Pink & White 50 mg./50 mg.	Pink Flesh & White 100 mg./50 mg.
1976 (Oct.-Dec.)	7,441,000	4,645,500	1,076,000
1977	34,480,800	9,611,100	945,100
1978	50,013,500	14,059,100	1,354,800
1979	70,706,100	19,363,900	1,699,800
1980	83,019,400	22,310,400	1,838,500
1981	90,939,700	23,673,600	1,946,100

Bolar's decision to market generic versions of the APRESAZIDE combinations was based, at least in part, on the commercial success that CIBA-GEIGY had achieved with those products.

From October 1976 through 1981, the number of patients taking APRESAZIDE products for hypertension also increased steadily.

As a result of their commercial success, CIBA-GEIGY's APRESAZIDE products have become the third largest seller in the CIBA Pharmaceutical line of ten anti-hypertension products and the fifth largest seller in the entire CIBA Pharmaceutical line of forty-one prescription products.

As a result of CIBA-GEIGY's long, continuous and exclusive use of the trade dress for its APRESAZIDE products, its extensive promotional efforts and the commercial success that its APRESAZIDE products have achieved, physicians who regularly prescribe APRESAZIDE products have come to associate the trade dress of those capsules with the brand name APRESAZIDE as representing a single source of supply. Moreover, because anti-hypertensive drugs are usually taken on a daily basis for an extended period of time and because the

medication's name is routinely typed or written by the pharmacist on the patient's vial, many patients taking APRESAZIDE products have come to associate the trade dress of those capsules with the brand name APRESAZIDE as representing a single source of supply although not with the particular manufacturer.

C. *Bolar's Look-Alike Products*

On March 4, 1982, Bolar received FDA approval in the form of an approved ANDA to market combination products containing hydralazine hydrochloride and hydrochlorothiazide in the same fixed ratios as CIBA-GEIGY's APRESAZIDE products. The ANDA's approved labeling indicated that Bolar intended to market these combinations in the same colors, sizes and shapes as CIBA-GEIGY's APRESAZIDE capsules.

Although Bolar claims that it selected its colors for reasons of public safety and public recognition, the court finds that Bolar deliberately copies the trade dress of CIBA-GEIGY's APRESAZIDE capsules for its own economic advantage.

Bolar claims that it copied the trade dress of CIBA-GEIGY's APRESAZIDE products in order to prevent injury and confusion on the part of patients who it claims identify the trade dress of their medications with the particular medical conditions for which they are prescribed. Wholesale and distributor customers would prefer Bolar to duplicate the trade dress of CIBA-GEIGY's APRESAZIDE products because doing so will facilitate generic substitution and thus increase the sales of Bolar's products. Patients are more apt to accept generic substitutions if the medication has the same appearance. They may reject such substitution if it does not. The court specifically finds that Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide combinations at the expense of CIBA-GEIGY's APRESAZIDE products.

D. *Likelihood of Confusion*

Bolar contends that the imprintation of its corporate logo and NDC Code Number on each of its hydralazine hydrochloride/hydrochlorothiazide capsules sufficiently distinguishes them from CIBA-GEIGY's APRESAZIDE capsules so as to obviate any likelihood of confusion among patients.

Realistically, the likelihood of confusion cannot be assessed by a side-by-side comparison of the plaintiff's and defendant's products. It is the overall physical appearance of defendant's trade dress which is critical. The vast majority of patients who take this type of medication do not or cannot identify their medication, or its source, by reference to the matter imprinted on the drug capsule or tablet. Most of such patients are over the age of 60 years and it is unlikely that they will have sufficiently acute eyesight to detect the difference between their usual medication and Bolar's products based on the imprintations on Bolars' capsules.

Furthermore, Bolar's contention is contrary to its assertion that such duplication will obviate patient resistance to lawful generic substitution. Indeed if patients would be able to distinguish the source by markings on the capsule itself, it is difficult to reconcile that contention with the claim that copying of the characteristics facilitates lawful substitution. On the one hand defendant asserts that copying reduces resistance because the patient will think he or she is receiving the same medication. On the other hand and quite inconsistently, defendant contends that the medications can be readily distinguished by examination of the capsule. The fact is that they cannot be so distinguished by the typical patient utilizing such medication.

E. *Nonfunctionality of APRESAZIDE's Trade Dress*

There was no medical, pharmaceutical or manufacturing reason which compelled Bolar to make its hydralazine hydrochloride/hydrochlorothiazide combinations in capsule

rather than tablet form or in the same color combinations as CIBA-GEIGY's APRESAZIDE products. CIBA-GEIGY's APRESOLINE-ESIDRIX product, containing 25 mg. of hydralazine hydrochloride and 15 mg. of hydrochlorothiazide, is made in tablet form, as is Bolar's generic version of this product. CIBA-GEIGY actually formulated and manufactured production batches of the products at issue here in tablet form.

Another drug manufacturer, Reid-Provident Laboratories, Inc. ("Reid-Provident"), is marketing its products in distinctively different colored capsules than APRESAZIDE and has been successfully marketing its green-colored capsules as generic alternatives to CIBA-GEIGY's APRESAZIDE products.

Since the commencement of this action, Bolar itself has been marketing the fixed combinations in suit in distinctly different colored capsules than CIBA-GEIGY's APRESAZIDE products; and Bolar admits that such sales will be profitable. However, such action may have resulted from the temporary restraining order in this matter. Accordingly, the court does not view it as appropriate to utilize such sales in determining this matter, since the alternative may have been necessitated by compulsion.

The FDA has taken the official position that "the appearance of drug products is [not] closely enough related to their safety and effectiveness that the Agency can, on the basis of its present experience, require that generic drug products duplicate the appearance of their innovator drug counterparts." Although the FDA has routinely approved new drug applications and abbreviated new drug applications for drug products that duplicate the color, size and shape of the innovator's product, it has declined to *require* such duplication and "has not taken action affirmatively to encourage similarity in appearance between innovator products and their generic versions."

The official position of the New Jersey Drug Formulary is that a drug's trade dress serves no therapeutic function. Thus, in a section addressed "To the Consumer," the Formulary states:

> You should understand that generic products often differ in color, shape or size from the better-known (and usually more expensive) brand name products. Such differences are to be expected; these differences do *not* affect how well the medication works.

The court specifically rejects the contentions by Bolar that CIBA-GEIGY's trade dress is functional because it distinguishes between strengths; or because it may be used for preliminary identification in overdose or poison incidents; or because it may be a secondary means of identification by pharmacists.

Bolar's principal functionality contention is that patients with chronic illnesses such as hypertension identify the trade dress of their medications with the medical condition for which they are prescribed and that, accordingly, it is necessary for general equivalents to duplicate the physical appearance of their brand name counterparts in order to prevent patient confusion and anxiety where legal generic substitution occurs.[6]

This resistance or anxiety theory has no application in cases where a patient is prescribed a particular medication for the first time and his pharmacist lawfully dispenses the generic equivalent. In such instances, even if the generic equivalent looks different than its brand name counterpart, the patient will neither be confused nor anxious since he or she has never been exposed to the brand name product's trade dress. To the extent that the patient in such circumstances identifies his medication's physical appearance with the condition for which it has been prescribed, he or she will do so by reference to the generic equivalent's trade dress.

Similary such theory has no application in cases where a patient who is already on a brand-name drug is given

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[6] The court has already noted the inconsistency of this position with the claim that Bolar's product is readily distinguishable by virtue of its own markings on the capsule.

the opportunity to switch to a generic equivalent but declines to do so. In these situations, which concededly occur and are consistent with the patient's right to exercise informed consent, the physician or pharmacist will honor the patient's preference and continue the patient on the brand-name product. Thus, there is no occasion for confusion or anxiety under these circumstances based on differences in trade dress because the patient is never dispensed the generic equivalent, and therefore no anxiety or resistance can develop.

Accordingly, the theory is applicable only to those cases in which generic substitution is authorized, and a patient already on a brand name product is then dispensed a different-looking generic equivalent. In this situation, the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed. However, the two physicians who testified at the hearing, Dr. Audrey G. Kriegman of CIBA-GEIGY and Dr. Herbert Silberner, Bolar's own expert, both agreed that as soon as the situation is explained to the patient (which is standard medical and pharmacy practice) the patient invariably accepts the explanation and his temporary anxiety is immediately dissipated.

If the fears and anxieties of the patient could not be quelled by such an explanation, it may well be that a finding of functionality would be mandated. For this reason, the court made specific inquiry of Bolar's expert on this very subject:

> THE COURT: . . . [S]uppose, for instance, the generic equivalent was a different size, color and shape than a brand name drug; what difference would that make?
>
> THE WITNESS: The difference would be primarily if he were to change from one drug to another. In other words, if the brand name were one size, shape and color and the generic were another, when he made the transformation from the brand name to the generic there would be an element of con[f]usion.

THE COURT: But that could be remedied, could it not, by your explaining to the patient that he or she was receiving the generic equivalent?

THE WITNESS: That is exactly what we have to do, yes, sir.

THE COURT: And has that, in your experience, satisfied the patient's hesitancy?

THE WITNESS: Once the patient has been explained, they will accept the different size, shape and color. But it requires an explanation.

In order to exercise informed consent to generic substitution, a patient is entitled to know in advance whether the generic equivalent is made by a different drug manufacturer than the brand name counterpart he has been taking.[7]

Bolar's entire theory rest on the improper assumtion that the patient will develop resistance or anxiety upon receiving a different looking pill than that which had previously been prescribed. That assumption does not accord with the facts or with the law in many states. As a matter of practice or requirement, either the physician or the pharmacist will advise the patient of the proposed generic substitution in advance. It would be a simple matter to advise the patient at the time that the medication may be different in appearance. Such procedure could assuage the patient before ever examining the medication and recognizing the change in appearance. The same result is accomplished if the difference in appearance is discovered for the first time after the generic drug is dispensed and the explanation follows rather than precedes receipt of the medication. The right of informed consent will be jeopardized if the generic equivalent looks identical or confusingly similar to the brand name drug, since Bolar's theory necessarily assumes that in such cir-

[7] The Illinois Formulary specifically provides that drug substitution may not occur unless, *inter alia*, the "informed" patient agrees to the substitution.

cumstances the patient will not be alerted to any difference in the two products.

Permitting generic drug manufacturers to sell identical copies of medication may deprive patients of the right to make such inquiry because they will be deprived of the opportunity to be informed of the facts (i.e. the difference in appearance) sufficient to warrant such inquiry. Therefore, the court rejects Bolar's functionality argument as being unsupported by the record and contradicted by the testimony of its own expert witnesses.

F. *Secondary Meaning*

Applying the well-settled legal criteria for determining secondary meaning to the court's foregoing fact findings concerning (a) the extended, continuous and exclusive use by CIBA-GEIGY of APRESAZIDE's trade dress; (b) the extensive and costly activities of CIBA-GEIGY in promoting its APRESAZIDE products and their distinctive and arbitrary trade dress; (c) the commercial success that CIBA-GEIGY's APRESAZIDE products have achieved in the market place; and (d) Bolar's intentional copying of APRESAZIDE's trade dress and the motivation for that copying, the court finds that CIBA-GEIGY has demonstrated a strong likelihood of ultimate success.

Bolar has advanced several arguments in opposition to CIBA-GEIGY's assertion that the trade dress of its APRESAZIDE products has acquire secondary meaning: *first*, that the mere existence of other blue and white, pink and white and pink flesh and white capsules on the market, albeit for non-antihypertensives and regardless of their sizes, shapes and shades, precludes a finding of secondary meaning in APRESAZIDE's trade dress; *second*, that in September 1974, CIBA-GEIGY allegedly copied the trade dress of Pfizer's yet to be marketed MINIPRESS products, at least for the blue and white 25 mg./25 mg. and the pink and white 50 mg./50 mg. APRESAZIDE capsules; *third*, that even if CIBA-GEIGY did not copy MINIPRESS's trade dress, the prior market

presence of Pfizer's blue and white 5 mg. and pink and white 2 mg. of MINIPRESS capsules, which are antihypertensives, precludes a finding of secondary meaning in the trade dress of CIBA-GEIGY's 25 mg./25mg. and 50 mg./50 mg. products; and *fourth*, that APRESAZIDE has become the common, descriptive name for all combinations of hydralazine hydrochloride and hydrochlorothiazide in the same fixed ratios as the products in suit or, alternatively, that CIBA-GEIGY has abandoned its federally-registered APRESAZIDE trademark.

1. *The Existence of Non-Antihypertensives Having the Same General Color Scheme as APRESAZIDE Capsules.*

Dr. O'Donnell conducted a survey of drug literature for Bolar, in the course of which he identified about fifty drug products appearing in blue and white capsules, about eight to ten appearing in pink and white capsules, and approximately two appearing in pink flesh and white. Bolar introduced only certain of these capsules into evidence at the hearing. While accepting their admission into evidence over the objection of CIBA-GEIGY's counsel, the court stated at the time that it was dubious about their probative significance. The court finds that these exhibits and the survey are irrelevant to the issues before the court and, hence, are entitled to no weight on this motion except for the MINIPRESS capsules, which shall be discussed hereafter. All other capsules clearly involve the proverbial comparison of "apples and oranges." Firstly, many of the identified capsules were either distinctly different shades of blue or pink or distinctly different sizes than CIBA-GEIGY's APRESAZIDE capsules. Secondly, Dr. O'Donnell admitted that not one of the ten exhibits contained active ingredients which were chemically, generically or pharmaceutically equivalent to those of APRESAZIDE products; and that, in fact, unlike APRESAZIDE products, not one of these exhibits was a product indicated for the treatment of hypertension. Indeed, two of the

products (Anacin-3 and Extra Strength Bufferin) are not even prescription drugs. None of these products could legally be substituted for APRESAZIDE products, even when the physician's prescription permits substitution.

2. *CIBA-GEIGY's Alleged Copying of MINIPRESS's Trade Dress*

Pfizer's MINIPRESS product is a prescription drug indicated for the treatment of hypertension which contains a single active ingredient, prazosin hydrochloride. MINIPRESS is marketed in a 1 mg. all-white capsule, a 2 mg. pink and white capsule, and a 5 mg. blue and white capsule. (D-1, D-2, D-12A). Bolar contends that in selecting the trade dress for its 25 mg./25 mg. and 50 mg./50 mg. APRESAZIDE products, CIBA-GEIGY deliberately copied the trade dress of Pfizer's 5 mg. and 2 mg. MINIPRESS products, thus negating a finding of secondary meaning. Although there is substantial evidence that CIBA-GEIGY carefully followed, investigated and monitored Pfizer's progress with said product, there is no evidence that CIBA-GEIGY deliberately copied the trade dress of any of Pfizer's capsules for MINIPRESS.

CIBA-GEIGY selected the capsule form and colors for its APRESAZIDE products in September 1974, two years before its products were actually marketed. In September 1974 Pfizer's MINIPRESS products were not yet on the market, being in the developmental stage about two years away from their commercial introduction in the United States. Accordingly, in order for Bolar's copying theory to succeed, there must be credible record evidence that Pfizer selected the trade dress for its 5 mg. and 2 mg. MINIPRESS products prior to CIBA-GEIGY's selection in September 1974, and that those responsible for the choice of APRESAZIDE's trade dress knew or had reason to know the form and colors in which the MINI-

PRESS products would ultimately be marketed. The record is barren of any such evidence.[8]

Apart from the fact that there is no proof of when Pfizer actually selected the final trade dress for its MINIPRESS products, the two CIBA-GEIGY officials responsible for the selection of APRESAZIDE's trade dress, Mr. Barnes and Mr. Marmaras, denied that they even knew in September 1974, the trade dress in which Pfizer would ultimately market MINIPRESS, much less that they copied that trade dress. There is no proof that CIBA-GEIGY had advance knowledge of the colors of Pfizer's MINIPRESS capsules as early as September 1974 or at any time before they were actually marketed.

In September 1974, CIBA-GEIGY did undertake to bring its APRESAZIDE products to the market on an "urgen[t]" basis. The urgency behind the APRESAZIDE project in 1974 was CIBA-GEIGY's concern that its leading anti-hypertensive product, SER-AP-ES, might be withdrawn from the market or lose substantial sales because of an alleged link between one of its components, reserpine, and breast cancer. But even if the urgency was to race Pfizer to the marketplace, such circumstances to not warrant a finding of deliberate copying by CIBA-GEIGY.

3. *The Market Presence of the Blue and White and Pink and White MINIPRESS Products*

Bolar also contends that the market presence of Pfizer's 5 mg. blue and white and 2 mg. pink and white MINIPRESS capsules, which started two months before

[8] Bolar has offered no plausible theory as to why CIBA-GEIGY, a brand name drug manufacturer, would have wanted to copy the trade dress of another brand name company's products even before those products had established any acceptance in the marketplace. Bolar contends that it has been deprived of discovery on this issue and that any similarity could not occur by chance. However, the court cannot substitute speculation for the uncontradicted testimony of plaintiff's witnesses.

APRESAZIDE's introduction in October 1976, precludes a finding of secondary meaning in the 25 mg./25 mg. and 50 mg./50 mg. APRESAZIDE capsules.

It is the overall appearance of MINIPRESS's trade dress that is critical for the resolution of this matter. Pfizer's 5 mg. blue and white MINIPRESS capsules are not similar in overall appearance to CIBA-GEIGY's 25 mg./25 mg. blue and white APRESAZIDE capsules. (Compare D-2 with P-2). Pfizer's blue and white capsules are noticeably larger than the CIBA-GEIGY blue and white capsules. Of course, such differences may not be readily apparent, because, as indicated above, a patient does not make a side-by-side comparison.

Insofar as the pink and white capsules are concerned, while the overall appearance of the Pfizer and the CIBA-GEIGY products are similar and while they are both antihypertensive, there is no real likelihood of patient confusion between the two. MINIPRESS contains a single active ingredient (prazosin hydrochloride) which is chemically, pharmaceutically and generically different than APRESAZIDE's two active ingredients (hydralazine hydrochloride and hydrochlorothiazide); moreover, MINIPRESS has no diuretic component while APRESAZIDE combines a thiazide diuretic with a direct-acting vasodilator. For this reason, no pharmacist could lawfully substitute MINIPRESS for APRESAZIDE, even if a physician's prescription allows substitution. Moreover, there is no reason to believe that a pharmacist would illegally substitute MINIPRESS for APRESAZIDE since they are comparable in price, thus removing the economic incentive for such conduct.

The similarity between APRESAZIDE and MINIPRESS does not preclude the trade dress of APRESAZIDE from acquiring secondary meaning. The trade dresses of APRESAZIDE and MINIPRESS products can both simultaneously achieve secondary meaning among two distinctly different groups of patients, APRESAZIDE users on the one hand, and MINIPRESS users on the other.

4. *Bolar's Claim that CIBA-GEIGY's APRESAZIDE Trademark has Become Generic or has been Abandoned*

Bolar itself has never used APRESAZIDE as the common descriptive name for its generic combinations of hydralazine hydrochloride and hydrochlorothiazide. On the contrary, Bolar has consistently recognized that hydralazine hydrochloride/hydrochlorothiazide is the common generic name for such products and has consistently used it as such. The record establishes that hydralazine hydrochloride/hydrochlorothiazide is the commonly recognized generic name of the products in suit, and that it has been "useful" enough for Bolar itself to utilize it as such. Moreover, CIBA-GEIGY itself has uniformly included hydralazine hydrochloride/hydrochlorothiazide as the established generic name for its APRESAZIDE branded products in all of its promotional literature disseminated outside of the company.

Equally unsupported is Bolar's claim of trademark abandonment by CIBA-GEIGY's alleged failure "to use the name APRESAZIDE in accordance with its corporate policy for maintenance and protection of its trademarks . . . ." The court has reviewed CIBA-GEIGY's corporate trademark protection policy as set forth in Exhibit D-4 and concludes that there is no evidence in the record which would indicate a material departure from this policy in the case of CIBA-GEIGY's APRESAZIDE trademark.

Bolar has introduced no evidence that CIBA-GEIGY either committed any acts of abandonment or had an actual intent to abandon its APRESAZIDE trademark.

G. *Bolar's Intent to Induce Illegal Substitution*

Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide products at the expense of CIBA-GEIGY's APRESAZIDE products.

Illegal substitution occurs when the physician's prescription precludes generic substitution, and yet the pharmacist, without advising the patient, nevertheless dispenses a generic equivalent and charges the same price he normally charges for the brand name counterpart. The economic incentive for such conduct is provided by the fact that generic drugs are usually less expensive to purchase at wholesale than their brand name counterparts.

The court finds that duplication of APRESAZIDE's trade dress would facilitate illegal substitution. Patients will not be alerted to illegal substitution if the generic equivalent's trade dress is identical to that of the brand name counterpart.

It is difficult to envision how legitimate substitutions would be adversely affected by a difference in appearance. Either before of after the substitution is made the patient is entitled to and would normally receive an explanation. Most would be satisfied with that explanation. There is no evidence to support rejection by patients based upon a difference in appearance after such explanation.

Why then does the defendant insist upon duplicating the appearance of plaintiff's product? There is a good likelihood that it is because Bolar recognizes that such identity facilitates illegal substitution.

By deliberately copying APRESAZIDE's trade dress, not only did Bolar have reason to anticipate the passing off of its look-alike products for CIBA-GEIGY's APRESAZIDE products, but there is a substantial likelihood that plaintiff will succeed in proving that Bolar actually intended to facilitate such illegal substitution among pharmacists in order to increase its sales. To reach any other conclusion would ignore the realities of the situation. The court recognizes that such an indictment could logically extend to any generic manufacturer who produced a look-alike drug. The facts of this case however indicate that there is a likelihood that the identity of appearance was intended, at least in part, to promote illegal not legal

substitution, since such identity is unnecessary to informed, legal substitution. Unfortunately the existence of illegal substitution has become all too prevalent.[9]

H. *Irreparable Harm and the Balance of Equities*

CIBA-GEIGY will sustain irreparable harm if preliminary injunctive relief is not granted. The balance of equities is in CIBA-GEIGY's favor.

Because illegal substitution is, by definition, undisclosed, CIBA-GEIGY will be unable to estimate accurately the full extent of its lost sales caused by Bolar's facilitation of this practice.

I. *The Public Interest*

By facilitating illegal substitution, Bolar's conduct places APRESAZIDE patients in jeopardy. Doctors have a right to demand and expect that their specific instructions shall be carried out. Defendant's look-alike drug permits the doctor's instructions to be easily thwarted. The patient

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[9] A total of 93 pharmacists and pharmacies in New York City, (27 in 1982 and 66 in 1980) have been criminally prosecuted and convicted for engaging in illegal substitution, while charges remain outstanding against another 61. The court takes judicial notice of these criminal convictions in this proceeding. *See* Fed. R. Evid. 201; *United States v. Alldredge*, 468 F.2d 684, 686 n.2 (3d Cir. 1972), *cert. denied sub nom. Martinez v. Alldredge*, 412 U.S. 920 (1973); *Ruth v. First Nat'l Bank*, 410 F. Supp. 1233, 1234 (D.N.J. 1976). While in *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 102 S. Ct. 2182, 2190 n.19 (1982), the Supreme Court recently expressed skepticism about the Second Circuit's taking judicial notice of indictments which "involved no convictions" and which were "not available when the district court rendered its decision", that is plainly not the situation here. Finally, there are cases in this circuit which have documented the existence of illegal substitution. *See SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055, 1059 (3d Cir. 1980); *Hoffman LaRoche, Inc. v. Premo Pharmaceutical Laboratories, Inc.*, 210 U.S.P.Q. 374, 380 (D.N.J. 1980); *Boehringer Ingerlheim G.m.b.H. v. Pharmadyne Laboratories*, 532 F Supp. 1040, 1059-60 & n.27 (D.N.J. 1980).

likewise has a right to expect that he or she will receive the exact medication prescribed. The existence of a look-alike drug deprives the patient of the sole means of learning that he or she is receiving a drug other than that prescribed. It may be unfair to the many ethical and honest pharmacists to predicate a rule of law upon an assumption that some pharmacists do and may illegally substitute generic drugs in order to make a greater profit. However, the evidence supports a finding that such practice is not uncommon and obviously may be more prevalent because of the inability to discover its extent.

Even in the case of legal substitution, Bolar's conduct endangers the public interest. If Bolar's products look confusingly similar to CIBA-GEIGY's, the patient may never learn or fully understand that they are not made by the same manufacturer as the products he had previously been taking—thereby jeopardizing his right to give his informed consent to the substitution.

A patient who has had a satisfactory experience with a drug may more readily agree to a generic substitute of the same appearance. At first blush, such conclusion may appear consistent with Bolar's arguments regarding functionality. However, such similarity may cause the patient to make the unwarranted assumption that the medication is identical and from the same manufacturer as the prior medication. In this area fraught with risks to health, no procedure should be condoned which affords to the patient anything less than all of the pertinent information and conditions which will prompt an inquiry for such information. There is no harm to the public in differentiating between the pills; there may be great harm in not.[10]

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[10] The court recognizes its obligation to review the record and make findings and conclusions independent of the proposed findings of facts and conclusions of law submitted by the parties. The court has complied with that obligation. However, the court found it extremely difficult to improve upon many of the submissions of the plaintiff in this matter, and to a large extent has adopted same

(Footnote continued on following page)

CONCLUSIONS OF LAW

On the authority of the Third Circuit's decision in *SK&F, Co. v Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), CIBA-GEIGY alleges that Bolar's intentional duplication of the trade dress of its APRESAZIDE products constitutes unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and two independent torts under New Jersey law: (a) the tort of "unprivileged imitation"; and (b) the tort of "passing off." The court has jurisdiction over CIBA-GEIGY's Lanham Act claims under 15 U.S.C. § 1121 and 28 U.S.C. § 1331(a) and over its New Jersey unfair competition claims under 28 U.S.C. § 1338(b) and the principles of pendent jurisdiction. In order to establish its entitlement to a preliminary injunction against Bolar's conduct, CIBA-GEIGY must demonstrate a likelihood of ultimate success as to at least one of these two claims. In addition, CIBA-GEIGY must demonstrate that it is threatened with irreparable injury absent such relief; and that the balance of equities and the public interest favors such relief. Applying the following legal principles to the foregoing fact findings, the court concludes that CIBA-GEIGY has satisfied this burden.

A. *Likelihood of Ultimate Success*

Bolar contends that CIBA-GEIGY has not met its burden with respect to either "unprivileged imitation" or "passing off" because, based upon Bolar's commercial labels and capsule markings, there is no likelihood that

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[10] *continued*
into its final opinion. The court trusts that the result will be recognized as a compliment to counsel's competence and thoroughness rather than any failing on the part of the court to consider fully and fairly all matters of fact and law presented to it.

After the initial reference to APRESAZIDE® and MINIPRESS®, the court has dropped the "®" symbol for ease of typing only. No legal significance should be attributed thereto for any reason.

its generic hydralazine hydrochloride/hydrochlorothiazide combination will be confused with CIBA-GEIGY's APRESAZIDE products. However, as recently reiterated in *Artus Corp. v. Nordic Co.*, 512 F. Supp. 1184, 1190-91 (W.D. Pa. 1981):

> The test for customer confusion is not whether the products can be differentiated when subjected to side-by-side comparison, but whether they create the same general overall impression. [citations omitted] . . . A dissimilarity in names will often prove ineffective in preventing confusion caused by the general similarity in appearance of the product.

Bolar's purported efforts to distinguish its product from plaintiff's are unsuccessful. The labels affixed by Bolar are not seen and the identification on the capsules cannot be seen. Furthermore, as noted in the court's findings of fact, on the one hand Bolar claims a readily apparent difference, and on the other hand urges that identity exists but is essential and justified.

The court concludes that neither Bolar's commercial labels nor the imprintations on its otherwise identical capsules are sufficient to prevent the likelihood of patients confusing Bolar's products with CIBA-GEIGY's. This is particularly so given the fact that most APRESAZIDE patients are over 69 years old. Here, as in *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories*, 532 F. Supp. 1040, 1046 (D.N.J. 1980), "[o]nly those with acute vision are likely to detect differences in logo, and a substantial number of [the drug's] users will not have sufficiently sharp eyesight." Having concluded that the record establishes a significant likelihood of confusion, the court next considers CIBA-GEIGY's chances of ultimate success with respect to the independent torts of unprivileged imitation and passing off.[11]

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[11] As the Third Circuit noted in *SK&F*, except for the federal law's interstate commerce requirement, "the elements of the unfair competition torts proscribed by New Jersey law and by section 43(a) of the Lanham Act are the same. . . ." 625 F.2d at 1066. And, here, the interstate commerce requirement is plainly satisfied.

1. *The Tort of Unprivileged Imitation*

As Judge Gibbons stated in *SK&F*, the elements of the tort of unprivileged imitation "are generally expressed as conjunctive requirements of secondary meaning and nonfunctionality." 625 F.2d at 1063. In *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 102 S. Ct. 2182, 2186 n.10 (1982), the Supreme Court noted that "[i]n general terms, a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." Expanding on this notion in *SK&F*, the Third Circuit had stated:

> Proof of nonfunctionality generally requires a showing that the element of the product serves no purpose other than identification. In the case of a drug, for example, the allegedly nonfunctional element must not enhance efficacy.

625 F.2d at 1063. Subsequently, in *Keene Corp. v. Paraflex Indus., Inc.*, 653 F.2d 822, 825 (3d Cir. 1981), the Third Circuit framed the appropriate inquiry as "the extent to which the design feature is related to the utilitarian function of the product or feature."

> When the design itself is not significantly related to the utilitarian function of the product, but is merely arbitrary, then it is entitled to protection as a design trademark if it has acquired the distinctiveness necessary to achieve secondary meaning.

Id. Applying these principles to the facts of this case, the court concludes that the trade dress of each of CIBA-GEIGY's three APRESAZIDE products is nonfunctional.

In affirming the district court's nonfunctionality finding in *SK&F*, the Third Circuit emphasized that "[t]he adoption of [DYAZIDE® 's] trade dress was arbitrary, having nothing to do with the purpose or performance of the drug, or with its processing." 635 F.2d at 1064. This court has already indicated its finding that this is equally true with respect to the trade dress of APRESAZIDE. There was no medical, pharmaceutical or manufacturing reason

that required CIBA-GEIGY to make its APRESAZIDE products in capsule rather than tablet form or in the particular colored capsules it selected. Nor was there any medical, pharmaceutical or manufacturing reason which compelled Bolar to copy the dosage form of color combinations chosed by CIBA-GEIGY.

The court rejects Bolar's contention that, because the three different color combinations of APRESAZIDE capsules serve to differentiate the capsules' three different strengths, their trade dress is functional. Rejecting a similar contention in *Ideal Toy Corp. v. Plawner Toy Manufacturing Corp.*, Civil No. 81-1431 (D.N.J. Oct. 21, 1981), *aff'd*, No. 81-3119 (3d Cir. July 26, 1982), this court stated:

> In the present instance, there are certainly numerous colors that could be used on the faces of the cube to differentiate them. In fact, it is not necessary to use solid colors at all. . . . The colors, of course, do serve a function. Some distinctive marks are necessary to differentiate the faces. But given the wide variety of possible marks, the actual colors and patches used are non-functional.

Slip Op. at 4. In *Biocraft Laboratories, Inc. v. Merck & Co.*, 532 F. Supp. 1068 (D.N.J. 1980), the court rejected the precise contention advanced by Bolar here. The fact that a manufacturer uses different colors to distinguish between its own products does not make those particular colors functional as to other manufacturers. If one strength is to be distinguished from another, any number and variety of colors or combinations thereof can be used. To suggest that the very same colors must be used is to defy common sense. Reid-Provident is presently marketing hydralazine hydrochloride/hydrochlorothiazide combination capsules which use different colors or shades to differentiate the products' three strengths but which do not duplicate the three color combinations of CIBA-GEIGY's APRESAZIDE capsules.

Bolar urges a number of other bases for concluding that CIBA-GEIGY's trade dress is functional. All of these con-

tentions are predicated upon the claim that such trade dress is utilized for identification purposes. It is inconceivable that a physician or a pharmacist would prescribe a drug based upon its appearance only. Such appearance may be utilized as a secondary or incidental means of identification, but such use hardly rises to the level of functionality which would mandate or permit copying.

As previously stated, the court likewise rejects Bolar's contention that APRESAZIDE's trade dress is functional as a means for identification in poison control or overdose situations. There is no proof that APRESAZIDE is the type of drug which is likely to engender the kind of emergency room visits where such identification would become necessary. *Cf. Boehringer Ingelheim G.m.b.H.*, 532 F.Supp. at 1049. Moreover, Bolar's own expert pharmacist testified that a drug's trade dress would rarely, if ever, be relied upon as the sole means of identification in such situations because of the "plethora" of similar-appearing medications on the market. *See also SK&F, Co.*, 625 F.2d at 1060.

The court has also rejected Bolar's anxiety-functionality contention and the related contention that APRESAZIDE's trade dress is functional because patients already taking the CIBA-GEIGY products identify the drug's physical appearance with the medical condition (i.e., hypertension) for which they are prescribed, based upon the foregoing findings of fact.

Based upon the foregoing findings of fact certain conclusions are warranted:

1. Obviously if a patient has never taken a particular drug, no special reliance upon trade dress arises.

2. Therefore, the claim of functionality can only pertain in those instances where a patient has taken a particular medication over an extended period of time.

3. Assuming the medication is successful, the patient will associate this effect with the drug and recognize it as beneficial.

4. The patient will identify such medication as being associated with the illness for which it was originally prescribed.

5. The constancy of the trade dress will permit the patient to identify it with a single source, although not the particular source.

6. If a generic equivalent is recommended and accepted, the patient will be informed.

7. If the generic drug is different in appearance, the patient will be advised or understand that it is coming from a different source.

8. The patient may accept the generic drug or reject it for that very reason or any other reason.

9. If the generic drug is identical in appearance, the patient may never know that it derives from a different source.

10. The fully informed patient can easily adjust to a new color scheme.

11. The dissimilar medication affords to the physician, the pharmacist and the patient the opportunity to differentiate between the name brand and generic product and make an informed decision; the look-alike may deprive them of that opportunity.

Despite the evidentiary record on this motion, which demonstrates to the court's satisfaction that APRESAZIDE's trade dress is nonfunctional as a matter of fact, Bolar nevertheless contends that the court is precluded from so finding as a matter of law under the Supreme Court's opinion in *Ives Laboratories, Inc.* The narrow issue in *Ives* pertained to the scope of appellate review and whether the Second Circuit had correctly reversed the district court's holding that defendant's duplication of plaintiff's trade dress for its CYCLOSPASMOL® product did not amount to contributory trademark infringement in violation of § 32 of the Lanham Act, 15 U.S.C. § 1114. In addressing that issue, the Supreme Court noted that

"[w]hile the doctrine of functionality is most directly related to the question of whether a defendant has violated § 43(a) of the Lanham Act" (the statutory provision upon which CIBA-GEIGY relies here), "a finding of functionality may also be relevant to an action involving § 32" since it tends to indicate "a legitimate reason for producing an imitative product." 102 S. Ct. at 2190 n.20. In that context, the Supreme Court held in *Ives* that the Second Circuit had committed reversible error by finding a § 32 violation without first rejecting the district court's factual finding of functionality as "clearly erroneous." *Id.* The very fact that the Supreme Court's reversal rested squarely upon the Second Circuit's failure to comply with the "clearly erroneous standard" of Rule 52(a) of the Federal Rules of Civil Procedure which, by its terms, applies to "findings of fact," demonstrates that the Court was *not* ruling that drug trade dress is functional as a matter of law. The Court held that the Second Circuit could not "substitute its interpretation of the evidence for that of the trial court" without complying with Rule 52(a)'s standard. 102 S. Ct. at 2190. As Justice O'Connor stated:

> The appellate court was not entitled simply to disregard the District Court's finding of functionality. . . . If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous.

Id. at 2190 n.20.[12] Therefore, this court concludes that *Ives* does not overrule *SK&F* with respect to the non-functionality of drug trade dress, as Bolar contends. Nothing in *Ives* precludes this court from evaluating the rele-

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[12] Indeed, the Supreme Court did not even view the district court's factual finding of functionality in *Ives* as dispositive of plaintiff's § 43(a) claim, in which context such a finding is admittedly "directly" relevant. Rather, because § 43(a) "prohibits a broader range of practices than does § 32," the Supreme Court remanded the case to the Second Circuit for an "independent review" of *Ives*' § 43(a) claim. *Id.* at 2190.

vant evidence and concluding that the trade dress here in issue is nonfunctional.

The second element of CIBA-GEIGY's "unprivileged imitation" claim requires proof of secondary meaning. In *Ives*, the Supreme Court observed that "[t]o establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself." 102 S. Ct. at 2186 n.11. As the Third Circuit explained in *Scott Paper Co. v. Scott's Liquid Gold, Inc.*, 589 F.2d 1225, 1228 (3d Cir. 1978):

> Secondary meaning exists when the trademark [or trade dress] is interpreted by the consuming public to be not only an identification of the product, but also a representation of the product's origin. [citations omitted]. Secondary meaning is generally established through extensive advertising which creates in the mind of consumers an association between different products bearing the same mark. This association suggests that the products originate from a single source.

In order to establish secondary meaning it is unnecessary to prove that the public identifies the products' trade dress with the name of the products' manufacturer. Indeed, such a requirement would render proof of secondary meaning virtually impossible in today's world since, as the Third Circuit has aptly recognized,

> owing to the ramifications of modern trade and international distribution of goods from the manufacturer to the jobber or importer and retailer to the consumer, the source or origin of the goods bearing a well-known trademark is seldom known to the consumer.

Family Circle, Inc. v. Family Circle Associates, Inc., 332 F.2d 534, 539 (3d Cir. 1964).

Accordingly, the law is well settled that:

> . . . to establish secondary meaning it is not necessary for the public to be aware of the name of the manufacturer which produces a product; rather, *it is sufficient if the public assumes that the product comes from a single though anonymous, source.*

Processed Plastic Co. v. Warner Communications, Inc., 675 F.2d 852, 856 (7th Cir. 1982) (emphasis added). Thus, it is no more necessary here for plaintiff to prove that APRESAZIDE patients identify those products with CIBA-GEIGY than it was for plaintiff to prove in *SK&F* that DYAZIDE® patients identified that product with SK&F.

A product is generally considered to have acquired distinctiveness and secondary meaning when its trade dress has been copied. This rule is based on the theory that one only copies something of value and would not copy the trade dress of a product if it does not afford some commercial gain. In determining whether a trademark or other symbol has acquired secondary meaning it is appropriate to consider the length and manner of its use and the nature and extent of advertising and promotions featuring the particular trade dress.

Secondary meaning can also be inferred by the court from the extensive sales of goods sold under the particular trade dress.

Applying these criteria to the facts, CIBA-GEIGY has demonstrated a strong likelihood of ultimate success on this element of its case. *See Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories*, 532 F. Supp. at 1055-56, 1063-64.

The court also rejects Bolar's contention premised upon the market presence of Pfizer's MINIPRESS capsules that CIBA-GEIGY's product is not entitled to secondary meaning. In order to acquire secondary meaning, a particular trade dress need not signify to all members of the

consuming public that the product emanates from a single, exclusive source. As the First Circuit explained in *President & Trustees of Colby College v. Colby College—New Hampshire*, 508 F.2d 804, 807 (1st Cir. 1975):

> In order to find secondary meaning the district court required proof that "the name 'Colby College' . . . exclusively signifies] the plaintiff institution in the mind of the public." [citations omitted.] Careful reading of both opinions suggests the court may have felt that exclusivity was lost if, to some persons, the name meant the wrong party. This is not so. . . . *There is sufficient secondary meaning as long as a significant quantity of the consuming public understand a name as referring exclusively to the appropriate party* . . . . (emphasis added).

Accordingly, the court concludes that the trade dress for APRESAZIDE's 25 mg./25 mg. and 50 mg./50 mg. capsules can achieve and has achieved secondary meaning among patients taking those products—the number of which is significant, despite the fact that patients taking MINIPRESS may associate the same color combinations with a different product and source. This conclusion is buttressed by the cases which have held that third-party use of a similar, if not identical trade dress or mark does not demonstrate a likelihood of confusion where, due to geographic barriers, distinct distribution channels, government regulations or the like, the probability is minimal that the consumers of plaintiff's products will ever be confronted with the third-parties' products. *See Dawn Donut Co. v. Hart's Food Stores, Inc.*, 267 F.2d 358, 364-65 (2d Cir. 1959); *National Lead Co. v. Wolfe*, 223 F.2d 195, 204 (9th Cir.) *cert. denied*, 350 U.S. 883 (1955); *David Crystal, Inc. v. Soo Valley Co.*, 471 F.2d 1245, 1246-47 (C.C.P.A. 1973); *Lever Brothers Co. v. American Bakeries Co.*, 537 F. Supp. 248, 254 (E.D.N.Y. 1982); *Central Bank & Trust Co. v. National Bank of Washington*, 187 U.S.P.Q. 651, 654 (D.D.C. 1975); *Modular Cinemas of America, Inc. v. Mini Cinemas Corp.*, 348 F. Supp. 578, 583 (S.D.N.Y. 1972). There is no real likelihood of APRESAZIDE pa-

tients ever being put in a position where they might confuse Pfizer's MINIPRESS products for their usual medication.

With specific reference to Bolar's affirmative defense of genericism, namely that the association between APRESAZIDE's trade dress and the products' trade name cannot prove secondary meaning because APRESAZIDE is a common descriptive name for the product in suit, Bolar's burden is a "heavy" one, particularly where, as here, the name under challenge is a federally registered trademark which carries a presumption of validity. *E.I. DuPont de Nemours & Co. v. Yoshida International, Inc.*, 393 F.Supp. 502, 523 (E.D.N.Y. 1975); *Coca-Cola Co. v. Pace*, 283 F. Supp. 291, 293 (W.D. Ky. 1968). In the context of CIBA-GEIGY's preliminary injunction motion, Bolar must demonstrate a probability that it will ultimately succeed at trial in carrying the burden of this affirmative defense. The court concludes that Bolar has not so demonstrated. This is particularly so in light of Bolar's own, consistent use of hydralazine hydrochloride/hydrochlorothiazide as the generic name of the product in suit, which is strong evidence that APRESAZIDE has not become the generic appellation. *See Salton Inc. v. Cornwall Corp.*, 477 F. Supp. 975, 986 (D.N.J. 1979). What more significant proof could there be than that the defendant, which is seeking to be a major competitor of the plaintiff, does not itself utilize plaintiff's brand name in a generic sense.

Bolar has similarly failed to demonstrate the requisite likelihood of ultimate success on its affirmative defense of trademark abandonment—a defense which, as the Third Circuit has recently held, "must be strictly proved." *United States Jaycees v. Philadelphia Jaycees*, 639 F.2d 134, 139 (3d Cir. 1981). Under the Lanham Act, 15 U.S.C. § 1127, a federally-registered trademark is deemed "abandoned":

> (a) When its use has been discontinued with intent not to resume. Intent not to resume may be inferred from circumstances. Nonuse for two consecutive years shall be prima facie abandonment.

(b) When any course of conduct of the registrant, including acts of omission as well as commission, causes the mark to lose its significance as an indication of origin.

Proof of abandonment under subsection (a) embodies the "twin requirement of non-use and intent to abandon." *United States Jaycees*, 639 F.2d at 138. Measured against the criteria for determining whether these twin elements have been satisfied, see *id.* at 139, the court concludes that CIBA-GEIGY has not abandoned its APRESAZIDE trademark within the meaning of subsection (a). For the same reasons, Bolar has failed to demonstrate a likelihood of ultimate success on an affirmative defense of abandonment within the meaning of subsection (b). There is no persuasive evidence of conduct by CIBA-GEIGY constituting non-use of its APRESAZIDE trademark of an intent to abandon that mark; nor is there any proof of conduct by CIBA-GEIGY which has caused its APRESAZIDE trademark to lose its significance as an indication of origin.

The court concludes that CIBA-GEIGY has established the requisite likelihood of ultimate success on the elements of nonfunctionality and secondary meaning to support the issuance of a preliminary injunction on its claim of "unprivileged imitation" under § 43(a) of the Lanham Act and New Jersey law. Having so concluded, although it is unnecessary for the court to assess CIBA-GEIGY's likelihood of ultimate success on its independent claim of "passing off," the court will proceed to address it for the sake of completeness in the event of possible appellate review.

2. *The Tort of Passing Off*

In *SK&F*, what constituted illegal "passing off" under § 43(a) of the Lanham Act and New Jersey law was the facilitation by defendant, through its intentional imitation of DYAZIDE's trade dress, of the "practice by some unscrupulous pharmacists of substituting less expensive generic drugs for the brand name drugs prescribed with-

out informing their customers and without passing along the benefit of the lower price." 625 F.2d at 1063. As the Third Circuit explained:

> [I]t has been held that it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form which the manufacturer *can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off.*

Id. at 1062 (emphasis added).

Accord, e.g., Hoffman LaRoche, Inc. v. Premo Pharmaceutical Laboratories, Inc., 210 U.S.P.Q. 374, 383 (D.N.J. 1980); *Boehringer Ingelheim G.m.b.H. v. Pharmadyne Laboratories*, 538 F. Supp. at 1058-59 (D.N.J. 1980).

The court concludes that Bolar, in copying APRESAZIDE's trade dress, reasonably anticipated that its look-alike capsules would be passed off by pharmacies as CIBA-GEIGY's APRESAZIDE products to a not insignificant degree. However, Bolar argues that the Supreme Court's decision in *Ives* "overruled" *SK&F*'s "reasonable anticipation" standard for the tort of passing off under § 43(a) of the Lanham Act.

The Supreme Court's reversal in *Ives* was limited to plaintiff's claim of contributory trademark infringement under § 32 of the Lanham Act, 15 U.S.C. § 1114. Indeed, the Court remanded the case to the Second Circuit for an "independent review" of *Ives'* § 43(a) claim, because that provision "prohibits a broader range of practices than does § 32, as may the state unfair competition law. . . ." 102 S. Ct. at 2190. They key passage is contained in the concluding paragraph of Justice O'Connor's majority opinion, which reads as follows:

> Although the District Court also dismissed Ives' claims alleging that the petitioners violated § 43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because § 43(a) prohibits a broader range of

> practices than does § 32, as may the state unfair competition law, the District Court's decision dismissing *Ives'* claims based upon those statutes must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion.

Id.

Accordingly, *Ives'* purported rejection of the "reasonable anticipation" standard was limited to § 32 claims of contributory trademark infringement, leaving unaffected, pending further review, the lower court decisions with respect to § 43(a)'s admittedly "broader" reach. Thus, *SK&F*'s "reasonable anticipation" standard for the tort of passing off under § 43(a) remains the law in this circuit.

Section 43 outlaws a broader range of practice than does § 32. Citing Judge Hastie's "leading" opinion in *L'Aiglon Apparel, Inc. v. Lang Lobell, Inc.*, 214 F.2d 649 (3d Cir. 1954), the Third Circuit in *SK&F* stated that "[i]t is well established that section 43(a) proscribes not only acts that would technically qualify as trademark infringement, but also unfair competitive practices involving actual or potential deception," including the tort of passing off. 625 F.2d at 1065. By putting in the hands of pharmacists, through intermediate wholesalers and distributors, a product which admittedly will facilitate illegal passing off, Bolar knowingly creates a real potential for deception, whether or not it is technically guilty of contributory trademark infringement.

Alternatively, even assuming that *SK&F*'s "reasonable anticipation" standard does not survive *Ives*, CIBA-GEIGY has demonstrated a likelihood of success in establishing that Bolar copied its trade dress with the intention, at least in part, to induce or permit illegal substitution. This is the higher standard for contributory infringement championed by Justice White, 102 S. Ct. at 2192 (White, J., concurring) and the one which Bolar contends the *Ives* majority in fact adopted. In the context of this motion, it is unnecessary for CIBA-GEIGY to satisfy its

ultimate burden of proving such an intent. All that is required is proof of a likelihood of ultimate success on that issue. Based upon the court's findings of fact, the court concludes that CIBA-GEIGY has made such a showing. There is a substantial lieklihood that CIBA-GEIGY will be successful in proving that although Bolar intended that its product would facilitate legal substitution, it also contemplated and intended that illegal substitution would take place as well.

In sum, applying either the "reasonable anticipation" or the actual "intent" standard, the court concludes that CIBA-GEIGY has established the requisite likelihood of success to support the issuance of a preliminary injunction on its independent claim of "passing off" under § 43(a) of the Lanham Act and New Jersey law.

B. *Irreparable Harm and the Balance of Equities*

Despite evidence of prosecution, and convictions, the extent of illegal substitution may never be known. Plaintiff's claim of irreparable injury is supported by defendant's anxiety theory. If patients will not be anxious because the generic product looks identical to the brand-name product, it is because the patient cannot and does not distinguish between them. Therefore, there would be no reason to complain since the patient will be unaware of the illegal substitution. Under such circumstances, the extent of such substitution can never be discovered, for the very reason that permitting the existence of an identical appearing product virtually destroys the ability to obtain satisfactory information.

The court concludes that it will be impossible for CIBA-GEIGY to calculate the full extent of any lost APRESAZIDE sales resulting from the illegal substitution facilitated by Bolar's conduct, since by definition such substitution will be undisclosed. This exacerbates the normally "difficult" problem of proving lost sales due to infringement.

In *SK&F*, the Third Circuit affirmed the district court's finding of threatened irreparable injury on the following ground:

> Unknowing or willful substitution [of Premo's product for DYAZIDE®] even if legally permissible would expose SKF not only to the risk of patient and physician dissatisfaction if the patient reacted to the substitute drug differently, but also to the risk of suit for the resulting consequences. In such a suit the striking similarity in appearance of the two products would make it unlikely that SKF, the deep pocket defendant, could prove that the harm was caused instead by Premo capsules, because the only proof as to the source would be the capsules long since digested by the patient.

625 F.2d at 1066.

The court is also obligated to balance the equities. It is difficult to envision what equities Bolar can assert. It knowingly copied plaintiff's product for the specific purpose of gaining an economic advantage thereby. It is or should be familiar with the law on this subject. Whatever actions it took, whatever expenses it incurred, it did so with full knowledge of the probable consequences. Its risks were known and calculated. Here, as in *SK&F*, Bolar's position "is almost totally devoid of equities." *Id.* As the court has already concluded, there was no functional reason which compelled Bolar to copy the trade dress of CIBA-GEIGY's products. Like Reid-Provident, Bolar could have begun marketing its hydralazine hydrochloride/hydrochlorothiazide combinations in March 1982 in differently colored capsules than APRESAZIDE, if not in tablet form, and achieved the same strong market position which it admits Reid-Provident has achieved.

C. *The Public Interest*

The primary basis for issuing an injunction in this matter, however, is protection of the public interest. Absent some harm or potential harm to the public, the courts

might be more inclined to permit the parties to wage these battles in the marketplace rather than in the courts. However, this case presents a typical instance in which the court's edict is necessary to protect the public which stands unrepresented in this proceeding.

Stated in its most simple form the public will be harmed by the existence of defendant's product because it permits, if not encourages, illegal substitution. As the court has already noted in its findings of fact, such a determination is not meant to be a condemnation of all pharmacists or even a large portion thereof. But the facts support a finding that the practice exists, and therefore we must deal with the realities. There are laws against turning back mileage indicators on used cars, not because all dealers do it, but because some have and will.

The court concludes that the public interest will be served by the issuance of a preliminary injunction which, in effect, will prohibit the facilitation of illegal substitution. Certainly if such illegal substitution was intended, all the more reason why injunctive relief is appropriate.

Even in the case of legal substitution, Bolar's conduct endangers the public interest by jeopardizing the consumer's admitted right to sufficient information so that he can give informed consent to such substitution. If the physician has authorized the substitution without informing the patient, the patient will never know, if the generic is identical to the brand-name product previously administered. Even under these circumstances the court does not believe that the patient should be deprived of the opportunity of recognizing that a change has taken place. The look-alike drug deprives the patient of that opportunity. That Bolar's look-alike products may be chemically and therapeutically identical to CIBA-GEIGY's APRESAZIDE products does not obviate this threat to the public's right of informed consent. For as the Supreme Court has held:

> If consumers or dealers prefer to purchase a given article because it was made by a particular manufac-

> turer or class of manufacturers, they have a right to do so, and this right cannot be satisfied by imposing upon them an exactly similar article, or one equally as good, but having a different origin.

F.T.C. v. Colgate-Palmolive Co., 380 U.S. 374, 388 (1965), *quoting F.T.C. v. Royal Milling Co.*, 288 U.S. 212, 216 (1933).

Finally, the court rejects Bolar's argument that the injunction sought by CIBA-GEIGY is "anticompetitive" in that it seeks to use the trademark laws to perpetuate an expired patent monopoly and thus stifle legitimate competition. This precise argument was made in *SK&F* and flatly rejected by the Third Circuit. *See* 625 F.2d at 1064-65, 1067.

CONCLUSION

The court holds that CIBA-GEIGY has demonstrated its right to a preliminary injunction against Bolar's duplication of the trade dress of CIBA-GEIGY's APRESAZIDE products and an order will be entered to that effect.

/s/ H. Lee Sarokin
U.S.D.J.

DATE: August 10, 1982

Original to Clerk, U. S. District Court
Copy to Counsel

Filed December 16, 1983

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant,

BOLAR PHARMACEUTICAL CO., INC.,

Counterclaim-Plaintiff,

v.

CIBA-GEIGY CORPORATION,

Counterclaim-Defendant.

* * * *

BOLAR PHARMACEUTICAL, INC.,

Plaintiff,

v.

CIBA-GEIGY, LTD.,

Defendant.

Civil Action No. 82-788
Honorable H. Lee Sarokin

ORDER ON CONSENT DISMISSING COUNTERCLAIMS AND CONSOLIDATING HEARING WITH TRIAL ON THE MERITS

This Court having held hearings on April 22, May 12 and June 15, 1982 on the motion of plaintiff Ciba-Geigy Corporation for preliminary injunction, plaintiff being satisfied with the sufficiency of its proof therein for purposes of a trial on the merits, and defendant believing it submitted sufficient evidence and made offers of proof therein to defeat plaintiff's claims at a trial on the merits, it is this 16 day of December, 1983,

ORDERED upon consent and stipulation of the parties that

(1) Each of the supplemental and amended counterclaims in this action, whether asserted against plaintiff or Ciba-Geigy, Ltd., and the claims for relief set forth in the Complaint under §32 of the Lanham Act, 15 U.S.C. §1114, are dismissed without prejudice and without costs or attorneys fees to any party.

(2) The hearings held on April 22, May 12, and June 15, 1982 on plaintiff's motion for preliminary injunction shall constitute the trial on the merits in this action.

/s/ H. Lee Sarokin
U.S.D.J.

The parties hereto, by their duly authorized attorneys, hereby consent to the entry of the above order.

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By /s/ _____
A Member of the Firm

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Attorneys for Counterclaim-
Defendant Ciba-Geigy, Ltd.

ORDER ON CONSENT DISMISSING COUNTERCLAIMS AND CONSOLIDATING HEARING WITH TRIAL ON THE MERITS

This Court having held hearings on April 22, May 12 and June 15, 1982 on the motion of plaintiff Ciba-Geigy Corporation for preliminary injunction, plaintiff being satisfied with the sufficiency of its proof therein for purposes of a trial on the merits, and defendant believing it submitted sufficient evidence and made offers of proof therein to defeat plaintiff's claims at a trial on the merits, it is this 16 day of December, 1983,

ORDERED upon consent and stipulation of the parties that

(1) Each of the supplemental and amended counterclaims in this action, whether asserted against plaintiff or Ciba-Geigy, Ltd., and the claims for relief set forth in the Complaint under §32 of the Lanham Act, 15 U.S.C. §1114, are dismissed without prejudice and without costs or attorneys fees to any party.

(2) The hearings held on April 22, May 12, and June 15, 1982 on plaintiff's motion for preliminary injunction shall constitute the trial on the merits in this action.

/s/ H. Lee Sarokin
U.S.D.J.

The parties hereto, by their duly authorized attorneys, hereby consent to the entry of the above order.

PITNEY, HARDIN, KIPP & SZUCH

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Filed December 23, 1983

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

Honorable H. Lee Sarokin
Civil Action No. 82-788

FINAL JUDGMENT AND ORDER

This Court having held hearings in this action on April 22, May 12, and June 15, 1982 on plaintiff's motion for preliminary injunction; the Court having heard and considered the evidence, offers of proof and arguments of counsel; the Court having filed its opinion on August 11, 1982 granting plaintiff's motion for preliminary injunction and having issued a preliminary injunction on October 4, 1982; the Court of Appeals for the Third Circuit having affirmed the grant of the preliminary injunction on October 14, 1983; the parties having consented to converting the hearings held on plaintiff's motion for preliminary injunction to the final trial on the merits; and the Court having concluded that on the present record and for the reasons set forth in its opinion of August 11, 1982, CIBA-GEIGY is entitled to final relief;

It is on this 22 day of December, 1983, ORDERED, ADJUDGED AND DECREED

A. That the preliminary injunction issued on October 4, 1982 is made permanent;

B. That judgment is entered in favor of plaintiff and against defendant on the claims for relief set forth in the Complaint under Section 43(a) of the Lanham Act, 15 U.S.C. §1125(a), New Jersey statutes Annotated Sections 56:4-1 and 56:8-2 and the common law of unfair competition of the State of New Jersey; and

C. That except for the judgment of this Court dated August 24, 1983 awarding fees and costs of $12,500.00 to plaintiff, each party shall bear its own costs and attorneys fees, and no party shall be awarded monetary damages.

/s/ H. Lee Sarokin, U.S.D.J.

We hereby approve the
form of this Order

BENDIT, WEINSTOCK & SHARBAUGH
Attorneys for Bolar Pharmaceutical Co., Inc.

By /s/ James F. Keegan
A Member of the Firm

PITNEY, HARDIN, KIPP & SZUCH
Attorneys for Ciba-Geigy Corporation

By /s/ Frederick L. Whitmer
A Member of the Firm

FEDERAL STATUTE INVOLVED

Section 43(a) of the Lanham Act
15 U.S.C. § 1125(a)

§ 1125. False designations of origin; false description or representation

(a) Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

NEW JERSEY STATUTES

ARTICLE 1. GENERAL PROVISIONS

56:4-1. Appropriation of name, brand, trade-mark, reputation or goodwill of maker by dealer in product of maker

No merchant, firm or corporation shall appropriate for his or their own use a name, brand, trade-mark, reputation or goodwill of any maker in whose product such merchant, firm or corporation deals.

56:8-2. Fraud, etc., in connection with sale or advertisement of merchandise or real estate as unlawful practice

The act, use or employment by any person of any unconscionable commercial practice, deception, fraud, false pretense, false promise, misrepresentation, or the knowing, concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise or real estate, or with the subsequent performance of such person as aforesaid, whether or not any person has in fact been misled, deceived or damaged thereby, is declared to be an unlawful practice; provided, however, that nothing herein contained shall apply to the owner or publisher of newspapers, magazines, publications or printed matter wherein such advertisement appears, or to the owner or operator of a radio or television station which disseminates such advertisement when the owner, publisher, or operator has no knowledge of the intent, design or purpose of the advertiser.

Filed July 7, 1982

UNITED STATES COURT OF APPEALS
SECOND CIRCUIT

At a Stated Term of the United States Court of Appeals in and for the Second Circuit, held at the United States Courthouse in the City of New York on the seventh day of July, One Thousand Nine Hundred and Eighty-Two.

Present: HONORABLE J. EDWARD LUMBARD,
HONORABLE WALTER R. MANSFIELD,
Circuit Judges.

IVES LABORATORIES, INC.,

Plaintiff-Appellant,

Dkt. No. 80-7314 -against-

DARBY DRUG CO., INC., INWOOD LABORATORIES INCORPORATED, MD PHARMACEUTICAL COMPANY, INC., PREMO PHARMACEUTICAL LABORATORIES, INC., RUGBY LABORATORIES, INC., and SHERRY PHARMACEUTICAL, INC.,

Defendants-Appellees.

Ives Laboratories, Inc. ("Ives") has moved for a stay of the mandate of this court issued pursuant to the decision of the United States Supreme Court filed June 1, 1982, reversing our judgment dated January 8, 1981. We had reversed a judgment of the Eastern District of New York, Nickerson, *J.*, dismissing the complaint which alleged that the defendants' manufacture and distribution of a generic drug identical in appearance to Ives' trademarked drug CYCLOSPASMOL violated its rights under §§32 and 43(a)

of the Lanham Act, 15 U.S.C. §§1114 and 1125(a), and New York unfair competition laws. Since we based our decision upon §32 of the Act the Supreme Court, in reversing and remanding the case, directed us to review the other claims, stating:

> "Although the District Court also dismissed Ives' claims alleging that the petitioners violated §43(a) of the Lanham Act and the state unfair competition law, the Court of Appeals did not address those claims. Because §43(a) prohibits a broader range of practices than does §32, as may the state unfair competition law, the District Court's decision dismissing Ives' claims based upon those statutes must be independently reviewed. Therefore, we remand to the Court of Appeals for further proceedings consistent with this opinion." 50 U.S.L.W. 4592, 4596 (Sup. Ct. June 1, 1982).

The other claims were fully briefed and argued upon the appeal leading to our January 8, 1981, decision, and have been considered. Further briefing and argument is therefore unnecessary.

We affirm the judgment of the district court dismissing the other claims, substantially for the reasons stated by Judge Nickerson in his April 15, 1980, decision, which is predicated upon his findings that the color and shape of defendants' generic cyclandelate look-alike capsules serve functional purposes (e.g., therapeutic effect and identification) and that Ives' trademarked capsules had not acquired a secondary meaning creating the likelihood that it might be perceived as the source of the product. See *American Footwear Corp. v. General Footwear Co.*, 609 F.2d 655, 664 (2d Cir. 1979). We cannot label these findings clearly erroneous. See *Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc.*, ... U.S. ....., 50 U.S.L.W. at 4596 n.20. For the same reasons the dismissal of the state law unfair competition claims must stand.

Accordingly the judgment of the district court is affirmed and the motion to stay the mandate is denied.

/s/ J. Edward Lumbard
U.S.C.J.

/s/ Walter R. Mansfield
U.S.C.J.

N.B. Since this statement does not constitute a formal opinion of this court and is not uniformly available to all parties, it shall not be reported, cited or otherwise used in unrelated cases before this or any other Court.

Opinion of the United States Court of Appeals for the Third Circuit

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 84-5056 and 82-5797

CIBA-GEIGY CORPORATION,

Appellee

v.

BOLAR PHARMACEUTICAL CO., INC.,

Appellant

ON APPEAL FROM THE UNITED STATES
DISTRICT COURT FOR THE
DISTRICT OF NEW JERSEY - NEWARK
(D.C. Civ. No. 82-00788)
District Judge: Honorable H. Lee Sarokin

Argued: June 13, 1984
Before: HUNTER and HIGGINBOTHAM,
Circuit Judges,
and GILES, *District Judge**
(Filed November 2, 1984)

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*Honorable James T. Giles, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

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OPINION OF THE COURT

HIGGINBOTHAM, A. LEON, JR., *Circuit Judge.*

This is an appeal from a final order of the district court granting appellee CIBA-GEIGY Corporation ("CIBA") a permanent injunction against appellant Bolar Pharmaceutical Company ("Bolar"). CIBA had previously obtained a preliminary injunction against Bolar after an evidentiary hearing before the district court. This court affirmed the preliminary injunction on appeal. After the affirmance, and based on the same

record developed in the evidentiary hearing for the preliminary injunction, the district court granted a permanent injunction. The question now presented is whether the district court erred in granting a permanent injunction. Because we believe the district court properly granted CIBA a permanent injunction, we will affirm.

I.

Since our decision affirming the preliminary injunction, Bolar has been eager to take this case to the Supreme Court where Bolar believes this matter would be resolved in its favor. Unfortunately, because Bolar has repeatedly sought a quick determination by the lower courts, this case might be a classic example of the old axiom that "haste makes waste."

Bolar petitioned the Supreme Court for a writ of certiorari after our affirmance of the preliminary injunction. *CIBA-GEIGY Corp. v. Bolar Pharmaceutical Co.*, 719 F.2d 56 (3d Cir. 1983). That petition was denied. 52 U.S.L.W. 3651 (U.S. Mar. 6, 1984) (No. 83-1163) Bolar returned to the district court and asked that the district court convert its hearing concerning the preliminary injunction into a final trial on the merits.

On December 23, 1983, Judge Sarokin, after reviewing the prior litigation history and this court's affirmance of his prelimary injunction, entered an order which provided, *inter alia:*

> the parties having consented to converting the hearings held on plaintiff's motion for preliminary injunction to the final trial on the merits; and the Court having concluded that on the present record and for the reasons set forth in its opinion of August 11, 1982, Ciba-Geigy is entitled to final relief;

It is on this 22nd day of December, 1983, ORDERED, ADJUDGED and DECREED

A. That the preliminiary injunction issued on October 4, 1982 is made permanent.[1]

CIBA-GEIGY Corp. v. Bolar Pharmaceutical Co., No. 82-788 (D.N.J. Dec. 23, 1983). Bolar, the loser below, petitioned this court for summary affirmance in order to get this case to the Supreme Court. We denied that request.

My reference to the axiom "haste makes waste" concerns the confusion created when a district court converts an opinion granting a preliminary injunction into an opinion granting a permanent injunction without expressly recasting its findings accordingly. The standard for this court reversing the issuance of a preliminary injunction is different from the standard for reversing a permanent injunction. Because the district court did not expressly recast its findings in terms of the legal standard applicable to a permanent injunction, that mechanical task is left to this court. Although we are able to so convert the district court's opinion, we would much prefer that the district court recast its own opinion in the language of the standard it is applying. This would eliminate the possibility of confusion as to what the district court intended and would, in the long run, promote judicial economy.

As tedious as the process might be for us, we believe it is necessary to ensure that the district court's conversion of its preliminary injunction does not become the basis of another appeal.

When issuing the findings and opinion on the preliminary injunction, the district court used traditional preliminary injunction language. As an

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1. In addition, the district court granted other relief not pertinent to this appeal.

example, it said, "even assuming that *SK&F*'s 'reasonable anticipation' standard does not survive *Ives*, CIBA-GEIGY has demonstrated a *likelihood of success* in establishing that Bolar copied its trade dress with the intention, at least in part, to induce or permit illegal substitution." *CIBA-GEIGY Corp. v. Bolar Pharmaceutical Co.*, 547 F. Supp. 1095, 1116 (D.N.J. 1982) (emphasis added). At other places in its opinion the district court used similar language couched in a preliminary injunction context.

When the parties agreed to "convert" the hearing on the plaintiff's motion for preliminary injunction to the final trial on the merits, the district court did not expressly change the language of its opinion preliminarily enjoining Bolar. It did so by reference, and the parties agreed to the district court disposing of the case in this manner. This reading is bolstered by the district court's order of December 16, 1983 wherein it stated,

> [t]his court having held hearings on April 22, May 12 and June 15, 1982 on the motion of plaintiff Ciba-Geigy Corporation for preliminary injunction, plaintiff being satisfied with the sufficiency of its proof therein for purposes of a trial on the merits, and defendant believing it submitted sufficient evidence and made offers of proof therein to defeat plaintiff's claim at a trial of the merits, it is this 16th day of December, 1983,
>
> ORDERED upon *consent and stipulation of the parties* that
>
> . . . .
>
> (2) The hearing held on April 22, May 12 and June 15, 1982 on plaintiff's motion for preliminary injunction shall constitute the trial on the merits in this action.

CIBA-GEIGY Corp. v. Bolar Pharmaceutical Co., No. 82-788 (D.N.J. Dec. 16, 1983) (emphasis added).

It is almost absurd to believe that the parties did not realize that the district court had implicitly converted its findings of a "likelihood of success" on the merits to findings of "success" on the merits. Moreover, none of the parties made any suggestion in their briefs or at oral argument on the appeal from the permanent injunction that the findings of the district court should be construed in any fashion different from the manner in which we have construed them. The parties in this case were concerned primarily with the sufficiency of the evidence and with the significance of *Inwood Laboratories v. Ives Laboratories* ("*Ives*"), 102 S. Ct. 2182 (1982) to their case.

CIBA believed it had met its burden of proof under any reading of *Ives* while Bolar believed that it had presented sufficient evidence to defeat CIBA's claim for the preliminary and final injunction. Indeed both parties were so convinced that they felt little need to alter in any significant respect the briefs they had filed in the appeal of the preliminary injunction. For example, Bolar stated,

> [e]xcept for minor changes which reflect the conversion of the preliminary injunction into a permanent injunction, its present brief is substantially identical to [its earlier brief.]

Bolar Motion to Consolidate at 3.

For the above reasons, in analyzing this case we have treated the district court's findings that plaintiff has demonstrated "likelihood of success" on the merits as findings that the plaintiff "succeeded" on the merits.

II.

In 1970 CIBA received a patent on the drug hydrazaline hydrochloride/hydrochlorothiazide, an

anti-hypertensive composed of hydralazine hydrochloride, a vasodilator, and hydrochlorothiazide, a diuretic. Until its patent was dedicated to the public in 1981, CIBA retained the exclusive right to produce and market the drug, which it sold under the registered trademark APRESAZIDE. CIBA chose to market its 25 mg./25 mg. dosage in a blue and white capsule, its 50 mg./50 mg. in a pink and white capsule, and its 100 mg./50 mg. dosage in a pink flesh and white capsule.

In August 1976, two months before CIBA first marketed APRESAZIDE, another company, Pfizer, Inc., first marketed another anti-hypertensive, Minipress. Minipress is sold in two dosages, one in pink and white capsules, the other in blue and white capsules. Due to differences in size, the pink and white Minipress capsule does not resemble the pink and white APRESAZIDE capsule. Although the blue and white Minipress capsule is similar in appearance to the blue and white APRESAZIDE capsule, the drugs are chemically distinct and prescribed to distinct groups of patients.

After CIBA's patents were dedicated to the public, Bolar began to manufacture hydrazaline hydrochloride/hydrochlorothiazide capsules the same size, shape and color as the 50 mg./50 mg. and 100 mg./100 mg. APRESAZIDE capsules.[2] Bolar produced the capsules with the intention that they would resemble APRESAZIDE capsules. Bolar capsules are identical to APRESAZIDE capsules except that each is imprinted with the name of its respective manufacturer.

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2. The combination of the shape, color, and size of each of CIBA's APRESAZIDE capsules constitutes its respective trade dress. CIBA seeks an injunction based on the copying of its capsules' trade dress. In this opinion, the terms "trade dress" and "color scheme" or "coloring" are used interchangeably.

CIBA, in marketing APRESAZIDE, followed normal industry practice. As APRESAZIDE can be obtained only with a prescription, CIBA directed advertising to pharmacists and physicians rather than directly to purchasers of anti-hypertensives. Bolar, in marketing its generic drug, has also followed industry practice by directing its advertising to wholesalers who sell to pharmacists who, in turn, may substitute the generic drug for APRESAZIDE on the advice of the prescribing physician and with the consent of the patient.

A pharmacist, when dispensing APRESAZIDE or its generic equivalent, removes the capsules from their original container and places them in another container bearing the pharmacist's label. As a consequence, the consumer sees no identifying marks other than the small imprints on the capsules themselves.

III.

CIBA brought this action in the United States District Court for the District of New Jersey under section 43(a) of the Trademark Act of 1946 ("Lanham Act" or the "Act"), 15 U.S.C. § 1125(a) (1982), and under New Jersey's unfair competition law, N.J.S.A. 56:4-1 (1964 and Supp. 1984). CIBA asserted two violations of § 43(a), one derived from allegations that Bolar falsely designated the origin of its generic drug by manufacturing it in capsules identical to those CIBA used for APRESAZIDE. The other derived from allegations that Bolar's manufacture and distribution of hydralazine hydrochloride/hydrochlorothiazide capsules identical to CIBA's APRESAZIDE capsules, with reasonable anticipation or the intent that they would be illegally substituted for CIBA's APRESAZIDE capsules, would constitute contributory trademark infringement (passing off) within the meaning of the federal statute.

The district court granted CIBA's initial request for a preliminary injunction and later granted CIBA's request for a permanent injunction. Bolar is thus prevented from advertising, distributing, or marketing its present generic version of APRESAZIDE.[3] 547 F. Supp. at 1118.

CIBA proved (1) that the trade dress of APRESAZIDE was non-functional; (2) that APRESAZIDE had acquired secondary meaning with an identifiable group of users of anti-hypertensives; (3) that Bolar could reasonably anticipate that some pharmacists provided with Bolar's generic hydralazine hydrochloride/hydrochlorothiazide would attempt to illegally substitute it for CIBA's APRESAZIDE; and (4) that Bolar copied CIBA's APRESAZIDE trade dress with the intent, at least in part, to facilitate the illegal substitution of the Bolar's generic drug for CIBA's brand name drug. Bolar initially moved this court for a summary affirmance so it could hurry to the Supreme Court. We denied Bolar's motion because this appeal involves a permanent injunction, which requires us to examine anew evidence that we found sufficient to uphold a preliminary injunction and which requires us to apply a different legal standard.

IV.

In deciding whether a permanent injunction should be issued, the court must determine if the plaintiff has actually succeeded on the merits (i.e. met its burden of proof). If so, the court must then consider the appropriate remedy. *See Evans v. Buchanan*, 555 F.2d 373 (3d Cir. 1977).

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3. Bolar, of course, could market a generic version of APRESAZIDE if it changed any aspect of its product's trade dress so as to clearly distinguish it from CIBA's APRESAZIDE trade dress.

Because this case involves claimed violations of federal law (§ 43(a) of the Trademark Act of 1946 (Lanham Act)) and New Jersey law (N.J.S.A. 56:4-1) as support for the grant of a permanent injunction, we must review both the state and federal claim in order to determine the proper scope of the injunction. If the district court correctly found that CIBA succeeded on the merits in its state claim, the district court's grant of a permanent injunction can only prevent Bolar's activity as it relates to New Jersey. That is, Bolar cannot necessarily be prevented from manufacturing and selling its product in California simply because its activity is unlawful in New Jersey. If, however, the district court correctly found CIBA succeeded on its federal claims, we must uphold the permanent injunction in its entirety so long as the balance of equities favors injunctive relief. We will consider first the claimed violations of New Jersey law, then the claimed violations of federal law.

A. *New Jersey Law*

CIBA claims two violations of New Jersey law by Bolar: unprivileged imitation and passing off.

Unprivileged Imitation

To establish unprivileged imitation under New Jersey law, a plaintiff must show (1) that an imitated feature of its product is non-functional, (2) that the imitation is likely to cause confusion as to the product's origin, and (3) that the product has acquired secondary meaning. *French American Reeds Manufacturing Co. v. Park Plastics Co.*, 20 N.J. Super. 325, 333-34, 90 A.2d 50, 54-55 (1952), *Press Publishing Co. v. Atlantic County Advertiser*, 108 N.J. Super. 75, 81, 260 A.2d 6, 9 (1969).

We begin our analysis with consideration of the district court's finding that the features imitated by Bolar are non-functional.

In *SK&F, Co. v. Premo Pharmaceutical Laboratories*, 625 F.2d 1055 (3d Cir. 1980), this court applied the correct standard for making a finding of nonfunctionality under New Jersey law. We stated:

> Proof of nonfunctionality generally requires a showing that the element of the product serves no purpose other than identification. In the case of a drug, for example, the allegedly nonfunctional element must not enhance efficacy.

Id. at 1063.

Judge Sarokin's finding of nonfunctionality is a finding of fact. A finding of fact is clearly erroneous when the reviewing court is left with the "'definite and firm conviction that a mistake has been committed.'" *Inwood*, 102 S.Ct. at 2189 (quoting *United States v. United States Gypsum Co.*, 333 U.S. 364 395 (1948)). We believe in this case appellant Bolar failed to prove that the district court's finding was clearly erroneous.

Regarding the issue of nonfunctionality, the district court found that CIBA had arbitrarily chosen to manufacture APRESAZIDE in blue & white and pink & white capsules and that no medical or business considerations compelled its choice. The district court noted that Reid-Prentice Laboratories, Inc., a third corporation, was successfully producing the same drug in a different color. Similarly, the district court found that no medical or business considerations compelled the size and shape of CIBA's APRESAZIDE capsule. As CIBA had asserted, the district court found that APRESAZIDE's capsule color, size and shape serve no purpose other than to identify APRESAZIDE as CIBA's product. The district court rejected Bolar's arguments concerning the alleged functionality of APRESAZIDE's trade dress, stating, "[t]he fact that a manufacturer uses different colors to distinguish between its own products does not make those particular colors functional as to other manufacturers." 547 F. Supp. at

1111. The district court also rejected Bolar's other functionality arguments, which were premised primarily on the assumption that physicians and pharmacists would prescribe a drug based on its appearance only. Based on this evidence we cannot say that the district court's finding of non-functionality was clearly erroneous.

We turn to the second necessary element of a successful claim of unprivileged imitation under New Jersey law -- that is, proving that the imitation is likely to cause confusion as to the product's origin in the eyes of the consuming public. Our standard of review on this issue is again the clearly erroneous standard. After carefully reviewing the record, we do not consider the district court's finding on this issue to be clearly erroneous.

The district court found that CIBA's APRESAZIDE capsules could not be distinguished from Bolar's generic imitation by the typical patient utilizing such medication. The district court reasoned as follows:

> Realistically, the likelihood of confusion cannot be assessed by a side-by-side comparison of the plaintiff's and defendant's products. It is the overall physical appearance of defendant's trade dress which is critical. The vast majority of patients who take this type of medication do not or cannot identify their medication, or its source, by reference to the matter imprinted on the drug capsule or tablet. Most of such patients are over the age of 60 years and it is unlikely that they will have sufficiently acute eyesight to detect the difference between their usual medication and Bolar's products based on the imprintations on Bolar's capsules.

547 F. Supp. at 1103.

We do not find any error in the district court's finding that Bolar's imitation of CIBA's APRESAZIDE

capsules is likely to confuse the relevant consuming public as to the product's origin.

Having decided that CIBA satisfied the first two essential elements of a successful claim of unprivileged imitation under New Jersey law, we turn to the final element -- whether the district court's finding that the trade dress of APRESAZIDE capsules had acquired a secondary meaning was clearly erroneous. The district court found that CIBA met its burden. We agree.

In *French American Reeds*, 20 N.J. Super. 325, 90 A.2d 50 (1952) the court set forth the standard for proving secondary meaning under New Jersey law. It stated that plaintiff must show that the article in question "'has become associated in the public mind with the first comer as manufacturer or source . . . .'" *Id.* at 334, 90 A.2d at 55 (quoting *Crescent Tool Co. v. Kilborn & Bishop Co.*, 247 F. 299, 300-301 (2d Cir. 1917) (L. Hand, J.)). Similarly, as this court stated in *SK&F*, if "[t]he only value of the trade dress was in identifying the goods with their source, . . . that value suffices in New Jersey courts to establish secondary meaning." 625 F.2d at 1064.

Thus, the district court applied the correct standard when it said, "It is no more necessary here for plaintiff to prove that APRESAZIDE patients identify those products with [CIBA] than it was for plaintiff to prove in *SK&F* that *Dyazide* patients identified that product with SK&F." 547 F. Supp. at 1113. Because the district court applied the correct legal standard, we must decide only whether the district court's finding that APRESAZIDE patients identify those products with CIBA is clearly erroneous. If we cannot say with firm conviction that its finding was clearly erroneous, we cannot reverse on this issue.

In concluding that secondary meaning had been acquired by CIBA's APRESAZIDE, the district court considered the duration of CIBA's exclusive manufacturing, the marketing and selling of

APRESAZIDE, CIBA's exclusive right to use APRESAZIDE as a trademark, the nature and extent of CIBA's advertising and promotions featuring APRESAZIDE's trade dress, the number of sales under APRESAZIDE's trade dress, and the extent of the copying of APRESAZIDE's trade dress. *See generally Ideal Toy Corp. v. Plawner Toy Mfg. Corp.*, 685 F.2d 78 (3d Cir. 1982).

Regarding these factors, the district court made the following observations:

> Since October 1976, CIBA-GEIGY has continuously marketed its APRESAZIDE products in the same trade dress, and for over five years, from October 1976 to March 1982, it was the sole pharmaceutical company which marketed these combination products in the particular trade dress described.
>
> From October 1976 to date, CIBA-GEIGY, through its CIBA Pharmaceutical Company division, has spent and continues to spend substantial sums of money advertising and promoting its APRESAZIDE products to physicians, pharmacists and hospitals. During the period October 1976 through 1981, CIBA-GEIGY's expenditures for the distribution of free samples and for promotional and medical literature, films, symposia and seminars promoting its APRESAZIDE products were in excess of $9 million. In addition, during this same period, the cost attributable to the efforts of the CIBA Pharmaceutical Company sales force in promoting APRESAZIDE products was over $16 million.

547 F. Supp. at 1101 (footnote omitted). Moreover, CIBA's sales of APRESAZIDE capsules have increased steadily since their market introduction. In addition to making these findings, the district court reasoned that

"[a] product is generally considered to have acquired distinctiveness and secondary meaning when its trade dress has been copied." *Id.* at 1113. The district court "specifically [found] that Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide combinations at the expense of [CIBA's] APRESAZIDE products." *Id.* at 1102. The district court also placed great significance in Bolar's "consistent use of hydralazine hydrochloride/hydrochlorothiazide as the generic name of the product in suit," 547 F. Supp. at 1114, in finding that patients associate APRESAZIDE with one source. *See Salton Inc. v. Cornwall Corp.*, 477 F. Supp. 975, 986 (D.N.J. 1979).

In this case, association between APRESAZIDE's trade dress and the trade name APRESAZIDE and CIBA is sufficient to prove secondary meaning. The name APRESAZIDE is more than a descriptive term. APRESAZIDE is a federally registered trademark that carries a presumption of validity. *See E.I DuPont de Nemours & Co. v. Yoshida International, Inc.*, 393 F. Supp. 502, 516 (E.D.N.Y 1975); *Coca Cola Co. v. Pace*, 283 F. Supp. 291, 293 (W.D. Ky. 1968). The district court rejected Bolar's claim that APRESAZIDE had become the generic appellation, thus CIBA alone is entitled to use "APRESAZIDE" as the name of its product.

Given (1) CIBA's exclusive sale of APRESAZIDE; (2) the fact that "APRESAZIDE" is a registered trademark; (3) the extent of advertising and sales of APRESAZIDE; (4) Bolar's copying, exactly, of APRESAZIDE's trade dress; and (5) Bolar's purpose in copying, we cannot say with firm conviction that a mistake was made by the district court in finding secondary meaning in APRESAZIDE's trade dress. Because the district court's finding of secondary meaning was not clearly erroneous, it therefore must be upheld.

Passing Off

In addition to establishing its New Jersey claim for unprivileged imitation, the district court concluded that CIBA succeeded on the merits of its New Jersey claim of passing off. The requisite proofs for passing off under New Jersey law have been recently articulated.

> [I]t has been held that it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off.

SK&F, 625 F.2d at 1062. *See also Boehringer Ingelheim v. Pharmadyne Laboratories*, 532 F. Supp. 1040, 1061 (D.N.J. 1980)(applying New Jersey law); *Merrell-National Laboratories v. Zenith Laboratories*, 194 U.S.P.Q. 157, 160 (D.N.J. 1977)(applying New Jersey law).

As noted previously, the exact copying of APRESAZIDE's trade dress and dosage levels for the blue & white and pink & white capsules has been established. Bolar copied CIBA's APRESAZIDE 25 mg./25 mg. blue & white capsule and 50 mg./50 mg. pink & white capsule. The district court also found that Bolar's purpose in copying was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide at the expense of [CIBA's] APRESAZIDE products. The district court found that Bolar's drug could be mistaken for APRESAZIDE. The district court took judicial notice of many convictions of pharmacists in New York for illegally substituting a generic drug for a brand name drug. 547 F. Supp. at 1108 n.9.[4] Finally,

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4. The conviction of at least 93 pharmacists and pharmacies for passing off in New York in the three years preceeding the

the district court found that Bolar's copying of APRESAZIDE was intended, at least in part, to facilitate pharmacists' illegal substitution of Bolar's look-alike for CIBA's APRESAZIDE.

It was not clearly erroneous for the district court to find, based on this evidence, that Bolar copied APRESAZIDE with the reasonable anticipation that pharmacists would illegally substitute Bolar's drug for CIBA's.

Having established that Bolar violated New Jersey's laws of unprivileged imitation and passing off, we turn to the equitable considerations to determine whether a permanent injunction was properly granted. The district court found that Bolar's look-alike drug deprives the patient of the principle means of differentiating between the drug she/he desires and that which is dispensed. The evidence supports a finding that the practice of illegal substitution occurs and that its full extent cannot be known. We agree with the district court that it may be unfair to the many ethical and honest pharmacists to predicate a rule of law upon an assumption that some pharmacists do and may illegally substitute generic drugs in order to make a greater profit, but we see very little harm to the drug manufacturers and pharmacists in this case where generic equivalents to APRESAZIDE can be manufactured in different sizes, shapes or colors without added cost.

Because of the significance of a permanent injunction, we quote the district court's reasoning regarding the public interest served by enjoining Bolar's imitation of APRESAZIDE's trade dress. The district court explained:

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filing of this suit was found probative of likelihood of illegal substitution in New Jersey. We cannot say that this inference, on the basis of the evidence presented, was improper.

> Even in the case of legal substitution, Bolar's conduct endangers the public interest. If Bolar's products look confusingly similar to CIBA-GEIGY's, the patient may never learn or fully understand that they are not made by the same manufacturer as the products he had previously been taking – thereby jeopardizing his right to give his informed consent to the substitution.
>
> A patient who has had a satisfactory experience with a drug may more readily agree to a generic substitute of the same appearance. At first blush, such conclusion may appear consistent with Bolar's arguments regarding functionality. However, such similarity may cause the patient to make the unwarranted assumption that the medication is identical and from the same manufacturer as the prior medication. In this area fraught with risks to health, no procedure should be condoned which affords to the patient anything less than all of the pertinent information and conditions which will prompt an inquiry for such information. There is no harm to the public in differentiating between the pills; there may be great harm in not.

Id. at 1109 (footnote omitted).

We believe that the district court's equitable finding concerning the public interest was not in error.[5] We also believe that the district court did not err in finding that Bolar violated the New Jersey laws

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5. In this case, as in many others, the district court was forced to perform a balancing test to identify the greater public interest. Bolar's argument that the copying of APRESAZIDE's trade dress is in the public interest is not necessarily a frivolous assertion, but the district court could find, without being in error, that the greater damage to the public would result from production of look-alike capsules.

prohibiting unprivileged imitation and passing off. Consequently, we will affirm the grant of the permanent injunction based on the district court's decision concerning New Jersey law.[6]

B. *Federal Law*

CIBA also asserted claims under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), for unprivileged imitation and passing off.

Unprivileged Imitation

To establish unprivileged imitation under the Act, a plaintiff must prove the nonfunctionality of the imitated feature and must prove secondary meaning of the imitated feature. These proofs are essentially the same as those required for unprivileged imitation under New Jersey law.[7] *SK&F Co. v. Premo Pharmaceutical Laboratories*, 625 F.2d at 1065. Because the district court's findings of fact with

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6. If a reviewing court, in interpreting federal law, determines that CIBA did not succeed on the merits of its federal claims, but did succeed on the merits of its New Jersey claims, the injunction issued by the district court will, in accordance with the full faith and credit clause, be valid only in New Jersey. We will affirm the granting of the permanent injunction based on the New Jersey claims fully aware of this fact.

7. "The federal law of unfair competition is not significantly different, as it bears upon this case, from that of New Jersey." *SK&F*, 625 F.2d at 1065. An assertion that *Ives* held that trade dress is functional as a matter of law is incorrect. *Ives* merely held that a circuit court cannot set aside a district court's finding of functionality simply because the reviewing court "might give the facts another construction." 102 S. Ct. at 2190 (quoting United States v. Real Estate Board, 339 U.S. 485, 495 (1950)). Indeed, in coming to its decision in *Ives*, the Supreme Court did not even consider the reasonableness of the district court's finding of functionality of trade dress.

respect to the New Jersey claim were not clearly erroneous, its findings of fact necessary to the proof of CIBA's federal claim were also not clearly erroneous. Thus, because CIBA succeeded on the merits of its New Jersey unprivileged imitation claim, it also succeeded on the merits of its claim under federal law. Even if an authoritative interpretation of New Jersey law suggests that the facts established do not prove a claim for unprivileged imitation under N.J.S.A. 56:4-1, an appropriate interpretation of § 43(a) of the Lanham Act indicates that the district court did not err in granting injunctive relief on the basis of CIBA's unprivileged imitation claim under the federal statute. In upholding this claim, we rely on our discussion of the evidence in the New Jersey law section of unprivileged imitation.

Passing Off

Bolar asserts that *Ives* changed the standard of proof for passing off under § 43(a) of the Lanham Act. It contends that *Ives*, properly read, requires a showing of intent on the part of the manufacturer to induce retailers to pass off imitative products when a § 43(a) claim is asserted. While it is debatable whether *Ives* altered the standard of proof for passing off under § 43(a), we need not decide the standard of proof issue. The district court's factual findings make that debate unnecessary. The factual findings and our review of them in this case differ markedly from the findings and their appellate review in *Ives*.

In *Ives*, the Court of Appeals for the Second Circuit was reversed because it "erred in setting aside findings of fact that were not clearly erroneous." 102 S.Ct. at 2190. The Supreme Court stressed that Fed. R. Civ. P. 52(a) "recognizes and rests upon the unique opportunity afforded the trial court judge to evaluate the credibility of witnesses and to weigh the evidence." *Id.* at 2188-89. In evaluating the credibility of witnesses and weighing the evidence, in *Ives*, the

district court's factual findings precluded any holding that there was a violation of section 32 of the Lanham Act. The trial judge in that case held that the materials before him could not "fairly be read" to suggest trademark infringement. *Ives Laboratories v. Darby Drug Co.*, 488 F. Supp. 394, 397 (E.D.N.Y. 1980).

In contrast to the findings made by the trial judge exculpating the generic drug manufacturer in *Ives*, the findings made by the trial judge in this case implicate Bolar and constitute the prerequisite predicate for holding that there was a violation of section 43(a) of the Lanham Act. Here, *inter alia*, the district court expressly found that Bolar's generic alternative could be mistaken for CIBA's APRESAZIDE, that many pharmacists had been convicted of illegal substitution in New York, that Bolar copied APRESAZIDE's trade dress with intent to increase sales of its generic alternative at the expense of CIBA, and that Bolar copied CIBA's trade dress with the intent, at least in part, to induce illegal substitution.[8] Irrespective of the analysis by the trial court as to the significance of footnote 13 in the *Ives* opinion, on the basis of the

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8. The trial judge's findings must be read in accordance with our discussion of the trial judge's conversion of the preliminary injunction to a permanent injunction. See pages 2-7 *supra*. In accordance with our discussion we read the trial judge's findings as follows:

> CIBA has demonstrated . . . that Bolar copies its trade dress with the intention, at least in part, to induce or permit illegal substitution. . . . CIBA [satisfied] its ultimate burden of proving such an intent . . . . [And, CIBA] proved although Bolar intended that its product would facilitate legal substitution, it also contemplated and intended that illegal substitution would take place as well.

547 F. Supp. at 1116.

record before us, we cannot say with definite and firm conviction that the trial court's finding of intent to facilitate illegal substitution was in error. Just as the trial judge should not have been reversed by the Court of Appeals in *Ives*, Judge Sarokin in this case, having had the opportunity to evaluate the credibility of witnesses and weigh the evidence, must be sustained on this issue because his findings are not clearly erroneous. We therefore affirm the district court's disposition of CIBA's federal passing off claim.

V.

Finally, the district court was not prevented from granting the injunction by CIBA's unclean hands. A successful unclean hands defense to an injunction proceeding requires a showing by defendant that plaintiff's conduct is inequitable and that it involves the subject matter of the plaintiff's claim. *Edelman v. Salomon*, 559 F. Supp. 1178, 1187 (D. Del. 1983). Bolar's assertions that CIBA marketed APRESAZIDE as a "step-two" drug when it is in fact a "step-three" drug,[9] that CIBA sold two adulterated batches of APRESAZIDE in 1976, and that APRESAZIDE's markings do not conform with FDA standards do not implicate transgressions so egregious as to merit the preclusion of an injunction. Moreover, the alleged

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9. A "step-two" drug is used in the second step of a series of treatment steps. A "step-three" drug is used in the third step of such treatment steps. CIBA's alleged motive in labelling APRESAZIDE a step-two drug was to increase the probability that it would be prescribed to patients suffering from hypertension (the number of hypertension patients reaching stage two being higher than the number reaching stage three). This allegation, as noted, does not bear upon the subject matter of the injunction proceeding and thus does not imply that the district court committed reversible error in granting the permanent injunction.

wrongdoings do not relate to the subject matter of Bolar's claim and, consequently, we cannot say the district court committed reversible error in rejecting Bolar's unclean hands defense.

VI.

For the reasons stated above, we will affirm the order of the district court granting CIBA a permanent injunction against Bolar.[10]

GILES, J., DISTRICT JUDGE, dissenting

I am unable to agree with the conclusions reached by the majority on the issues of secondary meaning and passing off. Accordingly, I respectfully dissent. Although the court below articulated the appropriate legal standard for secondary meaning under both New Jersey and federal law, it failed to apply properly that standard to the record evidence. With respect to passing off, I conclude that the majority should have decided what effect, if any, *Inwood v. Ives*, 102 S.Ct. 2182 (1982), has on the controlling precedent in this Circuit, *SK&F Co. v. Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980). Resolution of this issue would provide necessary guidance to the lower courts within this Circuit. In

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10. From our view, the thoughtful dissenting opinion has two faults: first, it devotes one-third of its discussion to an issue we did not decide and therefore we need not address this interesting theoretical problem. Its second and more serious flaw is that, despite its protestations to the contrary, in reality, the dissent refuses to accept the fact that we are bound by a prior ruling of this court, *SK & F*, 625 F.2d at 1055. As a panel of this court, we are obligated to follow a prior panel's construction of New Jersey law and as a panel we cannot reject those views simply because we think the prior case may have been wrongly decided.

addition, I conclude that there was insufficient evidence to support the district court's finding that Bolar copied the trade dress of APRESAZIDE with the intent to induce illegal substitution. Therefore, I would reverse the decision below and dissolve the permanent injunction.

As the majority points out, because the court below converted the injunction from preliminary to permanent without making any additional findings, we must view the previous determinations of likelihood of success on the merits as ultimate findings of success on the merits. That quantum of evidence which suffices for the grant of a preliminary injunction will not necessarily be sufficient for permanent injunctive relief. Therefore, we are obligated to review the record in this case afresh.

I. *SECONDARY MEANING*

To prevail on a claim of unprivileged imitation, CIBA must prove both nonfunctionality and secondary meaning. This is true under both the Lanham Act and New Jersey common law. *See e.g., SK&F*, 625 F.2d at 1062-63, 1065; *French American Reeds Mfr. Co., Inc. v. Park Plastics Co., Inc.*, 20 N.J. Super. 325, 333-34, 90 A.2d 50, 54-55 (1952). I agree with the majority's analysis and conclusions with respect to functionality. However, I am unable to agree that CIBA has proven that the trade dress of APRESAZIDE has acquired secondary meaning. Although the federal and state law is almost identical on this issue, I will analyze each.

A. *Federal Law*

To establish secondary meaning, "a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product, rather than the product itself." *Ives*, 102 S.Ct. at 2186 n.11 (citing

Kellogg Co. v. National Biscuit Co., 305 U.S. 111, 118 (1938)). *See also Fretxenet, S.A., et al. v. Admiral Wine & Liquor Co., et al.*, Nos. 83-5227; 83-5317, slip op. at 9 (3d Cir. March 28, 1984); *Ideal Toy Corp. v. Plawner Toy Mfr. Corp.*, 685 F.2d 78, 82 (3d Cir. 1982); *Scott Paper Co. v. Scott's Liquid Gold, Inc.*, 589 F.2d F.2d 1225, 1228 (3d Cir. 1978). This court stated in *Ideal Toy*: "[w]hen the primary significance of the trade dress *to a consumer* is in designating *not the product but its producer*, the trade dress has acquired secondary meaning." *Ideal Toy*, 685 F.2d at 82 (emphasis added). At the very least, it must be proven that the consumer links the trade dress with a single, albeit unnamed, source. *See Processed Plastic Co. v. Warner Comm., Inc.*, 675 F.2d 852, 856 (7th Cir. 1982); *Scott Paper*, 589 F.2d at 1228. Various factors have been held to be probative of secondary meaning, including the extent of sales and advertising, the length of use, buyer association and the fact of copying. *Ideal Toy*, 685 F.2d at 82.

In finding that CIBA had established secondary meaning, the district court relied primarily upon the factors identified in *Ideal Toy*, including the extensive advertising to promote APRESAZIDE, the continuous use of the trade dress, the drug's great commercial success and the fact of copying. *See CIBA-GEIGY v. Bolar Pharmaceutical Co., Inc.*, 547 F. Supp. 1095, 1101-102, 1105, 1113-14 (D.N.J. 1982). Likewise, the majority relies upon these factors in affirming the district court's conclusions on this issue. *See* Majority Opinion at 16-18. However, these factors are merely indicia of secondary meaning. Focus should not be diverted from the main inquiry -- whether the trade dress signifies the producer or source of the product in the minds of the public. The district court found that "patients taking APRESAZIDE products have come to associate the trade dress of those capsules with the

brand name APRESAZIDE as representing a single source of supply although not with the particular manufacturer." *CIBA*, 547 F. Supp. at 1102.[1] Thus, the association between the trade dress and the name APRESAZIDE was deemed sufficient to denote a single source. However, there was simply no evidence that patients link the word APRESAZIDE with a single, albeit anonymous source. Nor was there any evidence to suggest that patients recognized that the word APRESAZIDE was a brand name and registered trade-mark.[2] Rather than denoting *the* source or *a* source, the word APRESAZIDE probably identifies the product and its function, (*e.g.*, "my blood pressure medicine"), which is not sufficient for secondary meaning. *See Ives*, 102 S.Ct. at 2186 n.11; *Ideal Toy*, 685 F.2d at 82.

The promotional techniques necessarily employed by the pharmaceutical industry set it apart from more consumer-oriented fields. All promotional efforts are

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1. The district court also remarked that "it is no more necessary here for plaintiff to prove that APRESAZIDE patients identify those products with CIBA-GEIGY than it was for plaintiff to prove in *SK&F* that DYAZIDE patients identified that product with SK&F." *CIBA*, 547 F. Supp. at 1113. Although it is not necessary for the public to identify the trade dress with the particular named manufacturer, a link with a single source is required.

2. The majority states that the "association between APRESAZIDE's trade dress and the trade name *APRESAZIDE and CIBA* is sufficient to prove secondary meaning." Majority Opinion at 17 (emphasis added). Although APRESAZIDE is CIBA's trade-name, that does not indicate that the public associates that name with CIBA. Indeed, the court below specifically found to the contrary. *See CIBA*, 547 F. Supp. at 1102. The fact that only CIBA is permitted to use the name APRESAZIDE would not be probative of secondary meaning absent public recognition of this exclusivity.

directed at physicians and pharmacists, leaving the ultimate consumer uneducated as to the source of the prescription drug. On this score, I am persuaded by the observations and reasoning of Judge Nickerson in the district court opinion in *Ives*. He stated:

> No doubt to physicians and pharmacists the word "Cyclospasmol" signifies a source. But there is no reason to suppose this is so as to patients. They have not been the target of the sales campaigns, and they play no role in choosing what drugs to buy. Nothing in this record suggests that they 'understand by the word anything more than a kind of drug to which for one reason or another they [have] become habituated.' *Bayer Co. v. United Drug Co.*, 272 F.2d 505, 510 (S.D.N.Y. 1921) (L. Hand, J.). Such patients as read their prescriptions do not attribute to Cyclospasmol "any other meaning than as an ingredient in a general compound, to which faith and science might impart therapeutic virtue." *Id.*
>
> Thus, one cannot infer from the fact that patients recognize the name Cyclospasmol that they appreciate that the drug they receive comes from a single source. If they do not know that the word designates a single source, it follows that a color they associate with the name does not signify to them a single source and cannot acquire a secondary meaning.

Ives Laboratories, Inc. v. Darby Drug Co., Inc., 488 F.2d 394, 400 (E.D.N.Y. 1980), *rev'd on other grounds*, 638 F.2d 538 (2d Cir. 1981), *rev'd sub nom., Inwood v. Ives*, 102 S.Ct. 2182, *aff'd on remand*, 697 F.2d 291 (2d Cir. 1982).

In the context of the pharmaceutical industry, the *Ideal Toy* factors also become somewhat less

meaningful. The amount of advertising and promotion, which normally helps to familiarize consumers with a product, is not relevant as it is never seen by the public. Similarly, the volume of sales is not telling where the consumer does not *choose* the particular drug. The continuous use of the trade dress is unimportant unless the public recognizes that only one manufacturer uses that color, shape and size. The act of copying, standing alone, is not sufficient to prove secondary meaning.

In summary, there is no evidence on this record that the consuming public links the trade dress of APRESAZIDE with a single source, named or unnamed. Accordingly, I would hold that CIBA has failed to prove secondary meaning under federal law.[3]

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3. At first blush, my conclusion may appear contrary to this Circuit's decision in *SK&F*. There, the court concluded that the trade dress of SK&F's diuretic, DYAZIDE, had acquired secondary meaning. *SK&F*, 625 F.2d at 1064, 1065-66. There was evidence in *SK&F* that DYAZIDE was the only diuretic on the market which came in capsule form, the only one which was bi-colored and the only use using the color maroon. *Id.* at 1059. Here, there was evidence that Pfizer makes an antihypertensive, MINIPRESS, at least one strength of which is similar in appearance to APRESAZIDE. *See CIBA*, 547 F.Supp. at 1107. The district court found this irrelevant, as MINIPRESS and APRESAZIDE contain different ingredients and are both brand name drugs, thereby reducing the possibility of illegal substitution. *Id.* In *SK&F*, however, DYAZIDE was the *only diuretic* marketed with that appearance, including diuretics containing different ingredients and those produced by brand name as well as generic manufacturers. Arguably, this makes the case for secondary meaning stronger. Unfortunately, the *SK&F* court's analysis on this issue is virtually non-existent. Pointing to the distinctive trade dress and extensive advertising, the court concluded that "[t]he only value of the trade dress was in indentifying the goods with their source, and that value suffices in the New Jersey courts to establish

B. *New Jersey Law*

Under New Jersey law secondary meaning has been defined as the "identification of an object . . . with a single source -- even though unnamed -- and an interest on the part of the consuming public in buying because of that source." *Squeezit Corp. v. Plastic Dispensers, Inc.*, 31 N.J. Super. 217, 223, 106 A.2d 322 (1954). Similarly, in *French American Reeds Mfr. Co. v. Dark Plastics Co., Inc.*, 20 N.J. Super. 325, 90 A.2d 50 (1952), the Superior Court of New Jersey stated:

> [I]t is an absolute condition to any relief whatever that the plaintiff . . . show that the appearance of his wares has in fact come to mean that some particular person -- the plaintiff may not be individually known -- makes them, and that the public cares who does make them . . . . The critical question of fact at the outset always is whether the public is moved in any degree to buy the article because of its source and what are the features by which it distinguishes that source.

Kilborn & Bishop Co., 247 F. 299, 300-31 (2d Cir. 1917). Although the New Jersey test for secondary meaning is

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secondary meaning." *SK&F*, 625 F.2d at 1064. The court never addressed whether patients would link the distinctive maroon and white capsules to a single source.

Perhaps the court's rather conclusory treatment of the issue in *SK&F* arises from its procedural posture. *SK&F*, like the earlier decision in this case, *see* CIBA-GEIGY Corp. v. Bolar Pharmaceutical Co., 719 F.2d 56 (3d Cir. 1983), was reviewed after the grant of a preliminary injunction. The standard employed is a likelihood of success on the merits. Here, we are reviewing a final record to determine whether CIBA has produced sufficient evidence to prove secondary meaning. *SK&F* did not alter the traditional test for secondary meaning; it simply applied it in a different procedural context.

virtually the same as the federal standard, New Jersey law adds a second prong to the inquiry -- public interest. Therefore, CIBA would have to show not only the link with a single source, but also that the public wants that product *because* of the source. This would seem to entail some recognition that APRESAZIDE is a brand name, rather than a generic drug, and that its status as such makes it more desirable to the public. Although desirabilty may be inferred, it brings CIBA no closer to proving that the public associates the trade dress of APRESAZIDE with a particular or single source.

In *French American Reeds*, the court listed factors similar to the ones relied upon by the district court, including length of use, sales volume, advertising and "efforts to promote a conscious connection in the minds of the public between the product and its source."[4] 20 N.J. Super. at 337, 90 A.2d at 56. However, the court was quick to point out that these are only factors to be considered, not dispositive criteria establishing secondary meaning. The court explained that "[t]he ultimate test of secondary meaning must always remain whether plaintiff's product in its distinctive trade dress has become broadly known to the public as indicating a certain origin." *Id.* at 338, 90 A.2d at 57. I have previously concluded that there is no evidence to support a finding that the public associates the appearance of APRESAZIDE with a particular or single source. Therefore, CIBA has also failed to prove secondary meaning under the law of New Jersey.

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4. This factor parallels the "buyer association" elements of *Ideal Toy*, 685 F.2d at 82. As the previous discussion suggests, the marketing techniques of the pharmaceutical industry, vis-a-vis prescription drugs, render this factor useless.

II. *PASSING OFF*

In *SK&F*, this court held that liability could be imposed for passing off under section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a) (1982), and New Jersey law where it is proven that a drug is placed "in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product even if the manufacturer does nothing else to encourage passing off." *SK&F*, 625 F.2d at 1062, 1065-66. The *SK&F* court, like the court below and the majority here, concluded that it was reasonable to anticipate that duplication of a trade dress would facilitate passing off. *SK&F*, 625 F.2d at 1063; *CIBA*, 547 F. Supp. at 1116; Majority Opinion at 19. With this conclusion, I have no quarrel. A manufacturer can always reasonably anticipate that the act of copying a trade dress will make illegal substitutions easier. I question the continuing vitality of this "reasonable anticipation" test in light of the United States Supreme Court decision in *Ives*. Further, I conclude that the district court's alternate finding of intentional inducement under *Ives* is not supported by the record evidence. Moreover, it is necessary to consider what effect the demise of the reasonable anticipation standard has on this court's prediction of how the Supreme Court of New Jersey would decide state law on the subject.

A. *Ives and the Lanham Act*

Stating that "it is debatable whether *Ives* altered the standard of proof for passing off under § 43(a). . . ." the majority opinion refuses to reach the issue, relying instead upon the district court's alternate finding of intentional inducement. *See* Majority Opinion at 23. I share neither the majority's doubt nor hesitancy on this issue.

Ives was also a "look-alike" drug case. However, it was decided on the narrow ground of the appropriate standard of review.[5] Justice White, in a concurring opinion, took the majority to task for not deciding the issue presented in the petitions for certiorari -- whether the Second Circuit erred in applying the reasonable anticipation standard to a claim of contributory infringement under the Lanham Act. *Ives*, 102 S.Ct. at 2190-91 (White, J., concurring). Citing *Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924), Justice White characterized the reasonable anticiption standard as "watered down." *Id.* at 2191. He explained that "[t]he mere fact that a generic drug company can anticipate that some illegal substitution will occur to some unspecified extent, and by some unknown pharmacists, should not by itself be a predicate for contributory liability." *Id.* at 2192.

In response to Justice White's criticism, the majority stated that if the Second Circuit had relied upon the reasonable anticipation standard, "the court indeed would have applied a 'watered down' and incorrect standard." *Ives*, 102 S.Ct. at 2188 n.13.[6] Both the majority and concurrence agreed upon the proper legal test. Liability for passing off or contibutory infringement must be established by proof that the manufacturer intentionally induced another to pass off

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5. The actual holding of *Ives* is unremarkable -- a court of appeals may not set aside findings of the district court without a determination that they were clearly erroneous. *See Ives*, 102 S.Ct. at 2190.

6. The majority opined that the Second Circuit had not abandoned the traditional standard for passing off. The *Ives* majority stated that the reasonable anticipation language was simply used to buttress their conclusion that the test for contributory infringement had been met. 102 S.Ct. at 2188 n.13.

or continued to supply the product, knowing, or having reason to know, that the pharmacist was engaging in illegal substitutions. *See id.* at 2188, 2191-92 (White, J., concurring).

The passing off claim in *Ives* was brought under section 32 of the Lanham Act, while CIBA prosecutes the same claim in this case under section 43(a). The issue becomes whether the higher standard of intentional inducement should also be applied to section 43(a).

The *Ives* Court noted that "§ 43(a) prohibits a *broader range of practices* than does § 32 . . . ." 102 S.Ct. at 2190 (emphasis added).[7] A brief discussion of these two statutory provisions will illustrate that this simply means that section 43(a) proscribes a greater number of activities than does section 32. *See generally SK&F*, 625 F.2d at 1065 (discussing various types of behavior actionable under section 43(a)). On its face, section 32 is a very narrow provision, limited to action for infringement of a registered trademark.[8]

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7. In *Ives*, the section 43(a) claim was brought for unprivileged imitation and false designation of origin. The Court declined to rule on those claims, as they had not been reviewed by the court of appeals.

8. Section 32 provides, in pertinent part:

> (1) Any person who shall, without the consent of the registrant --
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> (a) use in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered mark in connection with the sale, offering for sale, distribution, or advertising of any goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive; or
>
> (b) reproduce, counterfeit, copy, or colorably imitate a registered mark and apply such

Although duplication of a trade dress is not, in itself, infringement of a trademark, the imitative appearance might induce a pharmacist to place a generic drug in a bottle bearing the brand name. Since the brand name is generally a registered trade-mark, the manufacturer can be held liable for contributory infringement of the inducement of passing off under this section. In contrast, section 43(a) does not require infringement of a mark, prohibiting instead any false designation of origin.[9] The mere act of trade dress duplication is

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reproduction, counterfeit, copy, or colorable imitation to labels, signs, prints, packages, wrappers, receptacles or advertisements intended to be used in commerce upon or in connection with the sale, offering for sale, distribution, or advertising of goods or services on or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive.

shall be liable in a civil action by the registrant for the remedies hereinafter provided. Under subsection (b) of this section, the registrant shall not be entitled to recover profits or damages unless the acts have been committed with knowledge that such imitation is intended to be used to cause confusion, or to cause mistake, or to deceive.

15 U.S.C. § 1114 (1982).

9. Section 43(a) provides:

Any person who shall affix, apply, or annex, or use in connection with any goods or services, or any container or containers for goods, a false designation of origin, or any false description or representation, including words or other symbols tending falsely to describe or represent the same, and shall cause such goods or services to enter into commerce, and any person who shall with knowledge of the falsity of such designation of origin or description or representation cause or procure the same to be transported or used in commerce or deliver the same to any carrier to be transported or used, shall be liable to a civil

actionable under this section if it tends to misrepresent a product's origin. Passing off is also actionable, affording a plaintiff like CIBA a choice of statutory remedies.[10] However, the nature of the activity, duplicating a drug's trade dress, and the potential for wrongdoing by an unscrupulous pharmacist, are the same regardless of which statutory section a plaintiff invokes. Consistency and logic dictate, therefore, that the same legal standard should be applied to the same behavior under both sections 32 and 43(a). To hold that a plaintiff need only prove reasonable anticipation under section 43(a) would render section 32 superfluous and eviscerate the intentional inducement standard of *Ives*. No plaintiff would voluntarily choose to proceed under section 32, given the higher burden under *Ives*, when they could invoke section 43(a) and be required to prove only reasonable anticipation. Moreover, the *Ives* court indicated that the standard for functionality is the same under both statutory sections. *See* 102 S.Ct. at 2190 n.20; *id.* at 2192-93 (White, J., concurring). It follows that the same must be true for "passing off." Thus, I would hold that *Ives* signaled the demise of the reasonable anticipation standard, implicitly overruling that portion of this court's decision in *SK&F*.

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action by any person doing business in the locality falsely indicated as that of origin or in the region in which said locality is situated, or by any person who believes that he is or is likely to be damaged by the use of any such false description or representation.

15 U.S.C. §1125(a) (1982).

10. Interestingly, a claim for contributory infringement or passing off fits more comfortably under section 32. The broader reach of section 43(a) is aimed at preventing, *inter alia*, confusion in the mind of the public. In light of the *Ives* decision with respect to section 32, it is not surprising that CIBA chose to proceed under section 43(a).

The district court did address the *Ives* intentional inducement standard, deciding in the alternative should this court hold that the *SK&F* reasonable anticipation standard was no longer viable. It found that Bolar copied the trade dress of APRESAZIDE with the intent to facilitate illegal substitutions. *CIBA*, 547 F. Supp. at 1108, 1116. In support of this finding, the court below explained that there was no legitimate reason for the duplication. *Id.* at 1108.[11] The only other evidence relied upon by the court was the conviction of ninety-three (93) New York pharmacies and pharmacists for illegal substitutions. *Id.* at 1108 n.9. This evidence was deemed sufficient by the majority in concluding that the district court's finding of intent to induce was not clearly erroneous. Majority Opinion at 24-25. I do not agree.

At the outset, I fail to see the relevance of the New York convictions. There is no evidence that these pharmacies had been passing off products produced by Bolar. Indeed, there was no suggestion that the convictions involved the illegal substitution of a generic for APRESAZIDE. These convictions may prove that illegal substitution is a problem, at least in New York, but, they prove nothing with respect to Bolar's actions or intent in duplicating the trade dress of APRESAZIDE.

The district court found that Bolar had the intent to induce illegal substitution. There was no finding of actual inducement. There is no claim that Bolar duplicated the packaging of its drug so that pharmacists might be innocently misled. Nor is there any evidence that Bolar said or did anything that could

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11. Having rejected the functionality of appearance, the court also tacitly rejected the argument that the similarity in trade dress would facilitate *legal* substitutions. *CIBA*, 547 F.Supp. at 1108.

be reasonably construed as encouraging illegal substitution. According to the language of *Ives*, the manufacturer must *intentionally induce* another to pass off or continue to supply goods to one whom it knows or has reason to know is passing off. *See* 102 S.Ct. at 2188; *id.* at 2191-92 (White, J., concurring) (emphasis added). This language requires some affirmative action apart from the act of copying. Such affirmative action is absent from this record.

Assuming that *Ives* punishes merely the *intent* to induce illegal substitution, the result remains unchanged. Proof of something in addition to the act of copying is required. It is beyond question that the *Ives* standard purports to have substantially more bite than the reasonable anticipation test. Under the latter, the act of copying proves the offense. By imitating the trade dress of a drug, it is virtually impossible to fail to anticipate that "it may be passed off as another product . . . ." *SK&F*, 625 F.2d at 1062. Thus, to satisfy the higher standard of *Ives*, it would seem that proof of something more than the act of imitation is required. However, under the district court's analysis, the same quantum of evidence which would satisfy the reasonable anticipation standard would also suffice to prove intentional inducement. Under either, the act of copying would prove the offense.[12] However, the rejection of the reasonable anticipation test by the *Ives* Court as "'watered down' and incorrect . . . .", 102 S.Ct. at 2188 n. 13, mandates that something in addition to the act of imitation is required to satisfy the intentional inducement standard. Since there is

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12. The district court recognized the effect of his ruling that duplication proved the intent to facilitate passing off. He stated "such an indictment could logically extend to any generic drug manufacturer who produced a look-alike drug." *CIBA*, 547 F.Supp. at 1108.

insufficient evidence to support the district court's finding of intent to induce. I conclude that this finding is clearly erroneous.

B. *New Jersey Law*

Relying upon *SK&F*, the majority assumes that the reasonable anticipation standard is the law of New Jersey. *See* Majority Opinion at 18. However, the court in *SK&F* sent out conflicting signals, first observing that New Jersey follows sections 711 and 713 of the Restatement (First) of Torts. Section 713 defines passing off, stating, "[o]ne fraudulently markets his goods as those of another if, though making no misrepresentation himself, he *intentionally induces* his purchasers to so market them." *SK&F*, 625 F.2d at 1062 (quoting Restatement (First) of Torts § 713 (1938)) (emphasis added). This language sounds strikingly similar to that employed in *Ives*. The *SK&F* court quoted the illustration following section 713, which was derived from *Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924). It must be noted that *Warner* was cited by both the majority and the concurrence in *Ives* as support for the intentional inducement standard. *See Ives*, 102 S.Ct. at 2188; *id.* at 2191 (White, J., concurring). The *SK&F* court then stated that the reasonable anticipation test "has been held . . . actionable . . . under New Jersey law . . . ." 625 F.2d at 1062 (citing *Merrell-National Labs., Inc. v. Zenith Labs., Inc.*, 194 U.S.P.Q. 157, 159-60 (D.N.J. 1977), *aff'd on other grounds*, 579 F.2d 786 (3d Cir. 1978)). Other than citing cases from other jurisdictions, decided under both state and federal law, the court engaged in no further analysis of the *Merrell* decision or New Jersey state Law.[13] *See SK&F*, 625 F.2d at 1062.

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13. The *SK&F* court never explained how the courts of New Jersey could adopt *both* the intentional inducement standard, as articulated in the Restatement, and the reasonable anticipation test.

While *Merrell* was a look-alike drug case, it differs from this case in that it involved actual passing off by pharmacists, as well as a claim for contributory infringement on the part of the manufacturers. With respect to the latter, that court found that there was no New Jersey precedent on point. *Merrell*, 194 U.S.P.Q. at 160. Thus, it had to "predict" how the Supreme Court of New Jersey would rule, if presented with a claim of contributory infringement. Looking at "general tenants" of New Jersey unfair competition law, the court concluded that "fair play has become the watchword . . . ." *Id.* The Court then discussed some rather dated federal cases which endorsed the reasonable anticipation standard. Based upon these cases and the "general tenants," the court concluded that plaintiff was likely to prevail against the manufacturers on a claim of unfair competition.[14] *Id.*

Nothing in the "general tenants" of New Jersey unfair competition law, as articulated by the *Merrell* court, tends to prove that New Jersey would adopt the reasonable anticipation standard over the test of intentional inducement. Indeed, the *SK&F* court's acknowledgment that New Jersey follows sections 711 and 713 of the Restatement (First) of Torts would indicate the exact opposite. The only insight provided by New Jersey courts is found in *dicta* in the *French American Reeds* case. The Superior Court of New Jersey noted that the action *did not* present questions of passing off or "fraudulent marketing," citing the Restatement (First) of Torts § 711 (1938). Quoting plaintiff, the court stated that the claim did "not involve any element of *actual intent* or *any attempt* on

---

14. *Merrell*, like *SK&F*, was decided in the context of preliminary injunctive relief. Although implicit in the holding, the *Merrell* court never articulated that it was predicting that New Jersey would adopt the reasonable anticipation standard.

respondents' part to see their goods as those of appellant." *French American Reeds*, 20 N.J. Super. at 329, 90 A.2d at 52. If reasonable anticipation were the standard in New Jersey, the plaintiff in *French American Reeds* might not have limited the case to claims of unprivileged imitation.

Discounting the so-called "general tenants" of unfair competition, the *Merrell* decision, upon which the *SK&F* court relied, is based upon an analogy to federal law. This analogy is no longer justified in the wake of *Ives*. Assuming the reasonable anticipation standard has been overruled as a matter of federal law, it follows that it cannot be viable under New Jersey law in the absence of any endorsement of that standard by the courts of New Jersey. I would hold that, in accordance with the Restatement (First) of Torts §§ 711, 713 (1938), and *Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924), New Jersey adheres to the traditional intentional inducement standard. For the reasons stated in the previous section, there is insufficient evidence to hold Bolar liable for passing off under this standard. Accordingly, I would reverse the decision below in its entirety.

A True Copy:

Teste:

Clerk of the United States Court of Appeals
for the Third Circuit

Order Amending Opinion

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

Nos. 84-5056 and 82-5797

CIBA-GEIGY CORPORATION,

Appellee,

v.

BOLAR PHARMACEUTICAL CO., INC.,

Appellant.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY-NEWARK

(D.C. Civ. No. 82-00788)

DISTRICT JUDGE: HONORABLE H. LEE SAROKIN

Argued: June 13, 1984

Before: HUNTER and HIGGINBOTHAM,
Circuit Judges,
and GILES, *District Judge**

(Filed November 2, 1984)

---

* Honorable James T. Giles, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

It is ordered that the opinion in the above-captioned matter, filed November 2, 1984, is hereby amended as follows:

1. page 7, paragraph 2, line 6, should read as follows:

   "Due to the differences in size, the blue and white Minipress capsule does not resemble the blue and white APRESAZIDE capsule. Although the pink and white Minipress capsule is similar in appearance to the pink and white APRESAZIDE capsule, the drugs are chemically distinct and prescribed to distinct groups of patients."

2. page 7, paragraph 2, line 4 should read as follows:

   "shape and color as the 25 mg./25 mg. and 50 mg./50 mg. APRESAZIDE capsules."

3. page 3, paragraph 3, line 3: replace "prelimary" with "preliminary";

4. page 9, paragraph 2, line 11: replace "of the Bolar's generic drug" with "of Bolar's generic drug";

5. page 17, paragraph 2, line 3: replace "principle" with "principal";

6. page 25, line 6: delete one "F.2d";

7. page 32, line 11: replace "anticiption" with "anticipation";

8. page 32, paragraph 2, line 7: replace "contibutory" with "contributory"; and

9. page 39, line 11: replace "oncluded" with concluded".

BY THE COURT

A. LEON HIGGINBOTHAM

Circuit Judge

DATED: December 21, 1984

A True Copy:

Teste:

Clerk of the United State Court of Appeals
for the Third Circuit

Order on the Mandate

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

HON. H. LEE SAROKIN

Civil Action No. 82-788

CIBA-GEIGY CORPORATION,

Plaintiff,

VS.

BOLAR PHARMACEUTICAL CO., INC.,

Defendant.

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED on this 15 day of February, 1985 that pursuant to the opinion of the United States Court of Appeals for the Third Circuit, filed on December 28, 1984, that judgment of the District Court is affirmed with costs in favor of CIBA-GEIGY Corporation in the sum of $231.84.

S/

H. LEE SAROKIN, U.S.D.J.

DATED: February 15, 1985

Filed 2/15/85
U.S.D.C. N.J.

PITNEY, HARDIN, KIPP & SZUCH
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Sur Petition for Rehearing

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

Nos. 84-5056 and 82-5797

CIBA-GEIGY CORPORATION,
Appellee,

v.

BOLAR PHARMACEUTICAL CO., INC.,
Appellant.

Present: ALDISERT, *Chief Judge,* SEITZ, ADAMS, GIBBONS, HUNTER, WEIS, GARTH, HIGGINBOTHAM, SLOVITER and BECKER, *Circuit Judges,* and GILES, *District Judge**

The petition for rehearing filed by Bolar Pharmaceutical Co., Inc., Appellant in the above-entitled case having been submitted to the judges who participated in the decision of this court and to all the other available circuit judges of the circuit in regular active service, and no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges of the circuit in regular active service not having voted for rehearing by the court in banc, the petition for rehearing is denied.

By the Court,

/s/ A. LEON HIGGINBOTHAM
Circuit Judge

DATED: January 8, 1985

* Hon. James T. Giles, United States District Court for the Eastern District of Pennsylvania, sitting by designation.

Judgment

UNITED STATES COURT OF APPEALS

FOR THE THIRD CIRCUIT

Nos. 82-5797 and 84-5056

CIBA-GEIGY CORPORATION,

Appellee,

vs.

BOLAR PHARMACEUTICAL CO., INC.,

Appellant.

(D. C. Civil No. 82-00788)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE ——— DISTRICT OF NEW JERSEY

Present: HUNTER and HIGGINBOTHAM, *Circuit Judges,* and GILES, *District Judge**

This cause came on to be heard on the record from the United States District Court for the ——— District of New Jersy and was argued by counsel June 13, 1984.

* Honorable James T. Giles, United States District Judge for the Eastern District of Pennsylvania, sitting by designation.

On consideration whereof, it is now here ordered and adjudged by this court that the Order of the said District Court, entered December 28, 1983, be, and the same is hereby affirmed. Costs taxed against appellant.

ATTEST:

SALLY P
Clerk

November 2, 1984

Costs taxed in favor of Ciba-Geigy as follows:

Brief ... $231.84

Certified as a true copy and issued in lieu of a formal mandate on January 16, 1985.

Test:

Chief Deputy Clerk, United States Court of Appeals for the Third Circuit.

Office-Supreme Court, U.S.
FILED
MAY 7 1985
ALEXANDER L. STEVAS,
CLERK

No. 84-1620

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

BOLAR PHARMACEUTICAL CO.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

On a Petition For A Writ of Certiorari To The United States Court Of Appeals For The Third Circuit

BRIEF OF *AMICUS CURIAE* THE NATIONAL COUNCIL OF SENIOR CITIZENS IN SUPPORT OF REVERSAL

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 84-1620

BOLAR PHARMACEUTICAL CO.,

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v.

CIBA-GEIGY CORPORATION,

Respondent.

On A Petition For A Writ of Certiorari To The United States Court Of Appeals For The Third Circuit

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BRIEF OF *AMICUS CURIAE* THE NATIONAL COUNCIL OF SENIOR CITIZENS

INTEREST OF THE NATIONAL COUNCIL OF SENIOR CITIZENS

The National Council of Senior Citizens (NCSC) of 925 15th Street, N.W., Washington, D.C. 20002, pursuant to Rule 36.1 of the Rules of the United States Supreme Court, files the attached brief Amicus Curiae on a Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

The National Council of Senior Citizens ("NCSC") is a not-for-profit membership organization of over four thousand affiliated local associations having a membership of over four million senior citizens.

The National Council of Senior Citizens advocates the interests of senior citizens concerning governmental regulations, legislation and judicial decisions in areas of health care that affect the elderly, particularly including decisions which will adversely affect the health care interests of senior citizens.

The National Council of Senior Citizens was initially formed as an advocate for proper health care for the elderly; it fought for enactment of the legislation establishing the Medicare program, and has vigorously opposed efforts to dilute that program. Recognizing that retired persons and other senior citizens cannot expect medical care superior to or more cost-effective than that which is available to all of the population, the four million plus senior citizens it represents are vitally interested in the quality and the cost of health care programs for all Americans.

One aspect of medical care that places a particularly heavy burden upon the elderly is the cost of medication. This cost is not adequately covered by Medicare or by the most widely used Medicare supplemental health insurance policies. Moreover, the cost of medication has been increasing more rapidly than cost of living increases in Social Security, upon which many elderly persons rely as a principal source of income.

It has been estimated that the elderly spend nearly 20 times more on pharmaceutical expenses, as a percentage of income, than the rest of the population. The National Council of Senior Citizens has both anecdotal and statistical evidence that the high cost of drugs is a burden upon the

elderly, which may in some cases even prevent senior citizens from following drug regimens prescribed for them. Often such drug regimens control symptoms or manage diseases so as to prevent more costly medical treatment.

The decisions of the lower courts in this case adversely affect the rights of senior citizens to purchase medication from competitive sources in the accustomed appearance which they use to recognize and identify their drugs. The elderly do not want to be forced to pay for exorbitant and unnecessary "detailing" and advertising costs and profits to a former patent monopolist, long after a patent has expired on a drug they need and want in recognizable form to maintain their health. The lower courts' decisions artificially establish one monopoly source for formerly patented drugs in their accustomed form.

NCSC has considerable anecdotal evidence from its members of the hardships which artificially inflated drug prices can impose upon them. NCSC, and the other major membership organizations of the elderly, provide pharmacy services at discount prices for their members and rely on the competition provided by generic drug manufacturers to reduce drug costs.

Appearance is important to medicine users. Many of the elderly follow their regimen by color codes—the "blue pill" and the "green pill" in the morning, and the "orange pill" at bedtime, etc. This habit is strong among many users, but is particularly strong among the elderly. The lower courts' decisions will interfere with the availability and utility of reasonably priced generic drugs to NCSC members, to others of the elderly population, and to all citizens.

Not only do the lower courts' decisions grant a monopoly on the very appearance which senior citizens use to recognize, identify, and distinguish among their medications, but

they also grant a monopoly on the *only useful* name provided by the former patent monopolist for the drug.

For these reasons, the NCSC believes that the intent of Congress and of the generic drug substitution laws of the various States is being circumvented, and the health of its members and other senior citizens is being endangered, by the lower courts' decisions.

ARGUMENT

I. The Lower Courts' Decisions Impede Competition By Granting A Perpetual Monopoly On The Reproduction Of A Feature Which Contributes Directly To The Sale Of The Underlying Product, And Are Contrary To The Public Interest

Consumers, particularly senior citizens, recognize and identify their drugs by the accustomed appearance of the drugs. When drug patents expire, senior citizens should be entitled to have competitors manufacture drugs in the accustomed dosage form of the drug. This right was clearly established by this Court in *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111 (1938) at page 120:

> Where an article may be manufactured by all, a particular manufacturer can no more assert exclusive rights *in a form in which the public has become accustomed to see the article* and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind. [emphasis supplied]

In its recent decision in *Inwood Laboratories, Inc. et al.*, v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982), this Court properly recognized the utility of drug appearance for drug identification, health and safety purposes unrelated to any

trademark purpose, in affirming the District Court decision:

> . . . that the blue and blue-red colors were functional to patients as well as doctors and hospitals: many elderly patients associate color with therapeutic effect; some patients co-mingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs. [456 U.S. at 853.]

The NCSC fully supports these factors of drug appearance utility approved by this Court in the *Inwood* case. These factors have been improperly disregarded by the lower courts in the Petitioner's case.

Moreover, the lower courts inaccurately characterized the public's interest in having generic drugs in the same color as the brand name, when they asserted that:

> Even in the case of legal substitution, Bolar's conduct endangers the public interest . . . . [S]uch similarity may cause the patient to make the unwarranted assumption that the medication is identical and from the same manufacturer as the prior medication.

Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc., 747 F.2d 844, 853 (3rd Cir. 1984), quoting *Ciba-Geigy Corp. v. Bolar Pharmaceutical Co., Inc.*, 547 F. Supp. 1095, 1109 (D.N.J. 1982). Generic drugs can be easily distinguished by their distinctively low prices. For example, generic Apresoline (an active ingredient in Apresazide used separately by some seniors), sells for only $2.61 for 100 25mg capsules, while its brand counterpart costs $13.61 for the same quan-

tity. Giant Drug Store Advertisement, *The Washington Post*, p. A-13, April 17, 1985.[1] The senior citizen who has been paying $13.61, and now is offered the same medication for $2.61, knows that he or she is getting the generic *without* even looking in the container. But when night comes and that senior citizen, alone at home, opens the container to take the usual "one little blue, two red and white, and one big orange", he or she shouldn't have to deal with a whole new color scheme to enjoy that cost saving.

The cost savings offered by generic drugs are desperately needed by senior citizens, many of whom live on fixed incomes. Bolar's efforts to sell a generic version of Apresazide at a lower price in a recognizable color is of great benefit to senior citizens and clearly is *beneficial* to the public interest. This concrete and important benefit overwhelmingly outweighs the mere speculative possibility that some pharmacist might somewhere risk criminal liability and loss of license by trying to cheat "patients . . . over the age of 60 years . . . [who don't have] sufficiently acute eyesight to detect the difference" between the clear imprint on the tablet, showing the source, and a mislabelled prescription. 747 F.2d at 851, quoting 547 F. Supp. at 1103. The pharmacists most seniors deal with pride themselves on helping seniors, on offering them the best service at the lowest cost, and, particularly, on offering them the lower cost generic alternative where it is available.

The outcome of these cases should not depend on which side of the Hudson River a "brand name" drug company decides to sue a generic drug manufacturer. The NCSC respectfully urges the Court to establish, throughout the

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[1]Current D.C. area ads do not list Apresazide prices, but an inquiry to the same chain indicates that the brand name currently sells for over 50% more than the generic.

United States, that the appearance of a drug product, which is the means consumers have had to recognize and identify the drug during the term of a patent monopoly, cannot continue to be monopolized under an unwarranted and improper extension of the trademark laws after expiration of a patent.

II. The Lower Courts' Decisions Grant A Monopoly On The Only Useful Name For A Prescription Drug

The District Court, affirmed by the Third Circuit Court of Appeals, in order to support its injunction, held that "Hydralazine Hydrochloride and Hydrochlorothiazide" is the generic name for the drug in suit. However, the only useful name known by consumers is "Apresazide", the claimed brand name.

None of the Ciba-Geigy's advertisements promoting "Apresazide" shows a useful generic name. Contrary to the court decision, a complicated list of ingredients—"Hydralazine Hydrochloride and Hydrochlorothiazide"—is not a useful generic name for senior citizens, or other persons, to remember and use as the name for their drug.

This decision conflicts with the policies of the Trademark laws and Food, Drug and Cosmetic laws by granting respondent a monopoly on the only useful name for a prescription drug. When enacting the trademark laws, Congress required that a name which is or becomes the "common descriptive name" of a drug not be monopolized as a trademark. 15 U.S.C. §§ 1064(c), 1065(4). Later, in 1962, because of drug companies' failures to list the generic name, or because of listing it in type too small a size, and because of abuses such as the spectacle of a large manufacturer of drugs failing to designate any generic name at all, Congress enacted 21 U.S.C. § 352(n) to require all prescription drug

promotions to have a generic name printed in type at least half as large as that used for the claimed tradename.[2]

Accordingly, it is the policy of the Trademark laws and the 1962 Amendments to the Food, Drug and Cosmetic laws to require "brand name" drug companies to provide and promote a generic drug name which can be remembered and used easily by persons who do not have a degree in pharmaceutical chemistry. The only useful name provided by Ciba-Geigy for senior citizens and other consumers is "Apresazide," which must necessarily be used as "the name for a drug in whose curative properties they had got confidence". *Bayer Co., Inc. v. United Drug Co.*, 272 F. 505, 510 (S.D.N.Y. 1921) (L.Hand). The decisions of the lower courts frustrate the policy of these laws.

III. The Lower Courts' Decisions Interfere With State And Federal Law And Policy Promoting Use Of Generic Drugs

The lower courts' decisions also interfere with the policy of state generic drug substitution laws enacted by all 50 states. Although the lower courts acknowledge that the known appearance of a drug facilitates patient acceptance and generic substitution by doctors and pharmacists, which is the purpose of the state generic substitution laws, the decisions nevertheless prohibit the manufacture and sale of such drugs.

That the judicial grant of a drug appearance monopoly interferes with the state substitution laws was argued by the New York Attorney General in his Amicus Brief in the

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[2]Respondent's advertising of its Singoserp, Nupercaine and Privine products was cited in Congress as an example of the practices which were to be prevented by the 1962 Amendments. Hearings before the Subcommittee on Antitrust and Monopoly of the Senate Committee on Judiciary, 87th Cong., 2nd Sess. (3374-3403) (1962) Trial R. at 982, 987-990.

Inwood case, and was acknowledged by Justice White in his concurring opinion in *Inwood Laboratories, Inc. et al. v. Ives Laboratories, Inc.*, 456 U.S. 844, 861 (1982):

> Preventing the use of generic drugs of the same color to which customers had become accustomed in their prior use of the brand name product interferes with the important state policy, expressed in New York and 47 other states, of promoting the substitution of generic formulations.

The lower courts' decisions also impede the policy of recent federal law to remove anti-competitive barriers to the marketing of generic drugs. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 ("the Act") to erase the "serious anti-competitive effects" of FDA's previous "cumbersome approval process" for generic drugs. H.R. Rep. 857, Part 2, 98th Cong., 2d Sess. at 4-5 (1984).

The Act was a response to widespread consensus that existing FDA procedures were obstructing rather than facilitating competition in prescription pharmaceuticals:

> Currently, there are approximately 150 drugs approved after 1962 that are off patent and for which there is no generic equivalent. All of these drugs could be approved in generic form if there was a procedure. Each year, more pioneer drugs go off patent and become available as generics . . . . Moreover, the lack of generics for post-1962 pioneer drugs will cost Federal and State governments millions of dollars.

H.R. Rep. 857, Part 1, 98th Cong., 2d Sess. at 17 (1984).

The Act expressed a national policy aimed at getting more generic drugs out on the market sooner:

- The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years. Older Americans, in particular, would benefit because they use almost 25 percent of all prescription drugs.

Id.

If brand name companies are permitted to monopolize the functional colors of their drug products, generic drug companies will be frustrated in their efforts to compete by selling for less money drugs with publicly familiar appearances, and Congress' efforts to support generic drug competition will be thwarted.

CONCLUSION

Amicus has a strong interest in encouraging competition within the pharmaceutical industry. Granting a perpetual monopoly on product appearance despite its functional character would seriously erode such competitive forces.

WHEREFORE, the National Council of Senior Citizens respectfully requests that this Court grant the Petitioner's request for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit.

Respectfully submitted,

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May 7, 1985

No. 84-1620

Office-Supreme Court, U.S.
FILED
MAY 8 1985
ALEXANDER L. STEVAS,
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

BOLAR PHARMACEUTICAL CO., INC.,
Petitioner,

—v.—

CIBA-GEIGY CORPORATION,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

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COUNTERSTATEMENT OF QUESTION PRESENTED

Does this case warrant the sparing exercise of this Court's extraordinary certiorari jurisdiction: (a) where the judgment affirmed by the Court of Appeals rested upon two *alternative* findings of liability under state as well as federal unfair competition law—the tort of "unprivileged imitation" and the tort of "passing off"; and (b) where, contrary to petitioner's assertion, neither finding is in conflict with this Court's decision in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*"), because:

—With respect to the tort of "unprivileged imitation":

(a) The Court of Appeals *affirmed* the trial court's *factual* finding of "nonfunctionality" as not being clearly erroneous, whereas in *Ives*, in the context of a claim of contributory trademark infringement, the Second Circuit *reversed* the trial court's *factual* finding of "functionality" *without* applying the clearly erroneous test; and

(b) The Court of Appeals *affirmed* the trial court's *factual* finding of "secondary meaning" as not being clearly erroneous, whereas in *Ives* this Court did not even address the sufficiency of the evidence necessary to establish "secondary meaning"; and

—With respect to the *alternative* holding of "passing off":

(a) The Court of Appeals explicitly did "not decide" the purported conflict between the trial court's application of the "reasonable anticipation" standard for the tort of "passing off" under § 43(a) of the Lanham Act and *Ives'* rejection of that test for contributory infringement under § 32 of the Lanham Act, the Court of Appeals instead holding that the trial judge's *factual* finding that petitioner acted with the intent to induce passing off 'differ[ed] markedly" from the factual findings in *Ives*

and "constitute[d] the prerequisite predicate" for a § 43(a) violation;

(b) *Ives* dealt only with the propriety of the "reasonable anticipation" standard for a claim of contributory infringement under § 32 of the Lanham Act and *not* for a claim of "passing off" under § 43(a) of the Act, which this Court noted in *Ives* "prohibits a broader range of practices than § 32"; and

(c) The District Court *alternatively* held that the "reasonable anticipation" standard governed the tort of "passing off" under New Jersey unfair competition law and that the facts supported such a state law violation—a finding that the Court of Appeals affirmed as not being clearly erroneous?

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CIBA-GEIGY Corporation, a privately-owned New York corporation, states that its parent is CIBA-GEIGY Ltd., a Swiss corporation. Each company's subsidiaries are wholly owned.

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

No. 84-1620

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

—v.—

CIBA-GEIGY CORPORATION,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

RESPONDENT'S BRIEF IN OPPOSITION

Respondent CIBA-GEIGY Corporation ("CIBA") respectfully submits that the instant Petition fails to present a single "special and important" reason warranting the issuance of a writ of certiorari. (*See* Sup. Ct. Rule 17). On the contrary, the only issue raised by the disposition below is whether the Court of Appeals correctly affirmed the District Court's findings of fact—which provided several *alternative* bases for its judgment under state and federal law—on the ground that those findings were not "clearly erroneous" under Rule 52(a) of the Federal Rules of Civil Procedure. Because that fact-bound determination presents no conflict with any decision of this Court or any other Circuit, and because this Court's extraordinary certiorari jurisdiction is not properly invoked "to review evidence and discuss specific facts,"[1] the Petition should be denied.

1 United States v. Johnston, 268 U.S. 220, 227 (1925).

STATEMENT OF THE CASE

The Petition presents an incomplete, misleading and distorted version of both the relevant facts and the proceedings below—not the least of which is its mischaracterization of the grounds for the Third Circuit's affirmance. The salient evidentiary facts are set forth in what the Court of Appeals described as the "thoughtful and detailed opinion" of the District Court (A. 4), and will not be repeated here except insofar as necessary to a proper understanding of the rulings below. Suffice it to say that the Petition presents a one-sided statement of the case, which largely ignores the District Court's fact findings and the substantial supporting evidence which led the Third Circuit to sustain those findings as not being clearly erroneous.[2]

A. The Preliminary Injunction Proceedings in the District Court

CIBA commenced this action on March 12, 1982, alleging that petitioner Bolar Pharmaceutical Co., Inc. ("Bolar") had violated both the federal and New Jersey state law of unfair competition by intentionally duplicating the trade dress of CIBA's brand name prescription drug APRESAZIDE.[3] On March 17, 1982, the District Court temporarily restrained

2 Similarly, the *amicus* briefs of the National Council of Senior Citizens, the Illinois Pharmacists Association and the Generic Pharmaceutical Industry Association ("GPIA") are replete with factual statements and assumptions which are not only outside of, but contrary to the record underlying the District Court's fact findings. As this Court recently noted, "[t]he stated desires of *amici* concerning the outcome of this or any litigation . . . are not evidence in the case, and do not influence our decision. . . ." Sony Corp. v. Universal City Studios, Inc., 104 S. Ct. 774, 785 n.16 (1984).

3 The term "trade dress" is used here, as it was by the courts below, in its "modern sense" to refer to the physical appearance of CIBA's APRESAZIDE products. *See* Ideal Toy Corp. v. Plawner Toy Mfg. Corp., 685 F.2d 78, 80 n.2 (3d Cir. 1982). "APRESAZIDE," a federally registered trademark, is CIBA's brand name for its antihypertensive combination products containing the drugs hydralazine hydrochloride and hydrochlorothiazide.

Bolar from selling its generic version of CIBA's product in confusingly similar trade dress and ordered Bolar to show cause why such conduct should not be preliminarily enjoined. (A. 10).

After a three-day evidentiary hearing at which seven witnesses testified and 162 exhibits were admitted into evidence (A. 11), the District Court granted CIBA's motion for a preliminary injunction. The reasons for the injunction's issuance were thoroughly set forth in a 41-page opinion which constituted the District Court's findings of fact and conclusions of law. (A. 8-50). In particular, the District Court held that CIBA was likely to establish at trial that Bolar's intentional duplication of APRESAZIDE's trade dress constituted two independent violations of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and the New Jersey law of unfair competition—the separate torts of "unprivileged imitation" and "passing off." (A. 35-44, 44-47). As the trial judge took pains to note, that determination was:

> . . . based upon a careful review of the entire record, an appraisal of the witnesses' credibility and demeanor and the reasonable inferences to be drawn therefrom. . . . (A. 11).

The District Court first addressed the two elements of "unprivileged imitation" under § 43(a) of the Lanham Act and New Jersey law—nonfunctionality and secondary meaning.[4] With respect to the former, the trial judge held that this Court's "narrow" ruling in *Inwood Laboratories, Inc.* v. *Ives Laboratories, Inc.*, 456 U.S. 844 (1982) ("*Ives*"), did not preclude it as a matter of law "from evaluating the relevant evidence and concluding that the trade dress here in issue is nonfunctional." (A. 39-40). And based upon that evidence, the

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4 Consistent with prior precedent, the trial judge noted that, "except for the federal law's interstate commerce requirement"—which was plainly satisfied—" 'the elements of the unfair competition torts proscribed by New Jersey law and by section 43(a) of the Lanham Act are the same. . . .' " (A. 34 n.11).

District Court found that the adoption of APRESAZIDE's trade dress "ha[d] nothing to do with the purpose or performance of the drug, or with its processing" and that there was "no medical, pharmaceutical or manufacturing reason" that had either required CIBA to select the trade dress or had compelled Bolar to copy it. (A. 19-20, 35-36).[5]

In finding that APRESAZIDE's trade dress was nonfunctional, the Court also rejected, on the facts before it, each of Bolar's functionality arguments, the "principal" one being that "patients with chronic illnesses such as hypertension identify the trade dress of their medications with the medical condition for which they are prescribed and that, accordingly, it is necessary for generic equivalents to duplicate the physical appearance of their brand name counterparts in order to prevent patient confusion and anxiety" unless illegal substitution occurs. (A. 21). Based on the testimony of Bolar's own medical expert, the District Court found that any "fears or anxieties of the patient" caused by a different-appearing generic equivalent are "invariably" allayed by an explanation from his physician or pharmacist—which is "standard medical and pharmacy practice"—and that any "temporary anxiety is immediately dissipated." (A. 21-23, 37-38). On the other hand, if the generic substitute is identical in appearance to the brand name drug, those patients who *choose* to remain on the brand name product but are dispensed the generic "may never know that it derives from a different source." (A. 38).

Turning to the second element of "unprivileged imitation," the District Court applied the "well-settled legal criteria for determining secondary meaning" to the record facts, and held

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5 In support of this conclusion, the Court found, among other things, that another pharmaceutical manufacturer "has been successfully marketing" distinctly different-colored capsules "as generic alternatives" to APRESAZIDE; that the Food and Drug Administration has "declined to *require*" that generic equivalents be sold in the same trade dress as their brand name counterparts; and that the New Jersey Drug Formulary has taken the "official position" that "differences [in appearance] do *not* affect how well the medication works." (A. 20-21; emphasis in original).

that CIBA had demonstrated "a strong likelihood of ultimate success" on this issue as well. (A. 24).[6] In brief, the Court based this finding on:

> (a) the extended, continuous and exclusive use by CIBA-GEIGY of APRESAZIDE's trade dress; (b) the extensive and costly activities of CIBA-GEIGY in promoting its APRESAZIDE products and their distinctive and arbitrary trade dress; (c) the commercial success that CIBA-GEIGY's APRESAZIDE products have achieved in the market place; and (d) Bolar's intentional copying of APRESAZIDE's trade dress. . . . (*Id.*)

With specific reference to the last factor, the District Court found that "Bolar deliberately copied the trade dress of CIBA-GEIGY's APRESAZIDE capsules for its own economic advantage" and that "Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its hydralazine hydrochloride/hydrochlorothiazide combinations at the expense of CIBA-GEIGY's APRESAZIDE products." (A. 18).[7]

As an *alternative* basis for its ruling, the District Court also held that CIBA had demonstrated the requisite likelihood of success with respect to the separate tort of "passing off" under both § 43(a) of the Lanham Act and New Jersey law. (A.

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6 In discussing the "well-settled" legal criteria for determining secondary meaning (A. 40-41), the trial judge expressly took account of this Court's *dictum* in *Ives* that "[t]o establish secondary meaning, a manufacturer must show that, in the minds of the public, the primary significance of a product feature or term is to identify the source of the product rather than the product itself." (456 U.S. at 851 n.11).

7 In holding in CIBA's favor on secondary meaning, the Court also rejected as unsupported Bolar's contention that "APRESAZIDE" had become the generic name of the products in suit, thereby rejecting Bolar's contention that patients' association of the APRESAZIDE brand name with the products' trade dress could not support a finding of secondary meaning. (A. 29, 43). On the contrary, the trial judge found that "[t]he record establishes that hydralazine hydrochloride/hydrochlorothiazide is the commonly recognized generic name of the products in suit" and that Bolar had "consistently used it as such." (A. 29).

44-47). In particular, based upon (1) the likelihood of confusion between APRESAZIDE and Bolar's look-alike capsules; (2) the "economic incentive" for pharmacists illegally to substitute Bolar's products for CIBA's; (3) the "all too prevalent" existence of illegal substitution by pharmacists;[8] and (4) the fact that "Bolar's principal motivation in deliberately copying APRESAZIDE's trade dress was to increase sales of its [generic equivalents] at the expense of CIBA-GEIGY's APRESAZIDE products," the trial judge found that Bolar's "duplication of APRESAZIDE's trade dress would facilitate illegal substitution" and that Bolar "reasonably anticipated that its look-alike capsules would be passed off by pharmacies as CIBA-GEIGY's APRESAZIDE products to a not insignificant degree." (A. 29-30, 31, 45, 47). On this basis, the Court concluded that CIBA was likely to prevail at trial on its claim of "passing off" under § 43(a) and New Jersey law, holding that the "reasonable anticipation" standard for that tort was unaffected by this Court's limited disposition in *Ives*. (A. 45-46).[9] Moreover, even assuming that *Ives* had been a "passing off" case under § 43(a)—which it was not—the District Court went on to find "alternatively" that "there is a substantial likelihood that plaintiff will succeed in proving that Bolar *actually intended* to facilitate . . . illegal substitution among pharmacists in order to increase its sales"; and that, accordingly, CIBA had satisfied even *Ives'* standard. (A. 30-31, 46-47; emphasis added).

Finally, the District Court concluded that an injunction against Bolar's conduct was "necessary to protect the public interest." (A. 49). Noting that "the public will be harmed by the existence of defendant's [look-alike] product because it permits, if not encourages, illegal substitution," the trial judge held that "the public interest will be served by the issuance of a

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8 In support of this conclusion, the Court took judicial notice of the fact that 93 pharmacists and pharmacies in New York City were recently *convicted* of engaging in illegal substitution, and that criminal charges remained outstanding against another 61. (A. 31 n.9).

9 *See* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1062-63 (3d Cir. 1980).

preliminary injunction which, in effect, will prohibit the facilitation of illegal substitution." (A. 49). And if Bolar actually intended such facilitation—which the Court found that CIBA had a substantial likelihood of ultimately proving—"all the more reason why injunctive relief is appropriate." (*Id.*) Moreover, the Court noted, "[e]ven in the case of legal substitution, Bolar's conduct endangers the public interest by jeopardizing the consumer's admitted right to sufficient information so that he can give informed consent to such substitution." (*Id.*)[10]

On the foregoing basis, the District Court entered an order preliminarily enjoining Bolar from "using any simulation, imitation or substantial duplication of [CIBA's] distinctive trade dress . . . in connection with . . . [Bolar's] hydralazine hydrochloride/hydrochlorothiazide products for the treatment of hypertension." (A. 6). Without seeking a stay of that injunction, Bolar appealed to the Third Circuit.

B. The Court of Appeals' Preliminary Injunction Affirmance and This Court's Denial of Review

On October 14, 1983, the Third Circuit, in a *per curiam* opinion, unanimously affirmed the District Court's preliminary injunction. (A. 3-4). Finding "no merit" to Bolar's arguments for reversal, the Court of Appeals stated:

> After reviewing the record, the briefs and arguments of the parties, and Judge Sarokin's thoughtful and detailed opinion, we hold that the district court did not abuse its discretion, commit an obvious error in applying the law, or make a serious mistake in considering the proof. (A. 4).

As for Bolar's contention that the district judge had erred in failing to read *Ives* as overruling the "reasonable anticipation"

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10 As the District Court noted, the Illinois Drug Formulary, among others, "specifically provides that drug substitution may not occur unless, *inter alia,* the 'informed' patient agrees to the substitution." (A. 23 n.7).

standard for the tort of "passing off" under § 43(a), the Third Circuit noted in a footnote that "we need not address this issue" because that standard was nevertheless "mandated" under New Jersey law; and because, in any event, under both § 43(a) and state law, the District Court's alternative holding with respect to "unprivileged imitation" provided "a sufficient independent basis for affirming the district court's grant of preliminary injunctive relief." (A. 4 n.1).

This Court thereafter denied Bolar's petition for certiorari to review the Third Circuit's preliminary injunction affirmance. 104 S. Ct. 1444 (1984).

C. The District Court's Entry of Final Judgment

In December 1983, at Bolar's urging and with CIBA's consent, the District Court converted the preliminary injunction hearings to "the final trial on the merits" and entered a final judgment in CIBA's favor. (A. 52-55). Concluding that "on the present record and for the reasons set forth in its opinion of August 11, 1982, CIBA-GEIGY is entitled to final relief," the District Court ordered that "the preliminary injunction issued on October 4, 1982 is made permanent." (A. 54-55). In so ruling, the District Court "implicitly converted its [earlier] findings of a 'likelihood of success' on the merits to findings of 'success' on the merits." (A. 66). Bolar then appealed again to the Third Circuit.

D. The Third Circuit's Affirmance and Denial of Rehearing *En Banc*

On November 2, 1984, the same Third Circuit panel which had unanimously affirmed the District Court's preliminary injunction this time affirmed its final judgment by a 2-to-1 vote.

At the outset, Judge Higginbotham, who was joined in the majority by Judge Hunter, identified the four key factual findings which formed the predicate for the District Court's

alternative holdings with respect to the torts of "unprivileged imitation" and "passing off":

> CIBA proved (1) that the trade dress of APRESAZIDE was non-functional; (2) that APRESAZIDE had acquired secondary meaning with an identifiable group of users of anti-hypertensives; (3) that Bolar could reasonably anticipate that some pharmacists provided with Bolar's generic hydralazine hydrochloride/hydrochlorothiazide would attempt to illegally substitute it for CIBA's APRESAZIDE; and (4) that Bolar copied CIBA's APRESAZIDE trade dress with the intent, at least in part, to facilitate the illegal substitution of Bolar's generic drug for CIBA's brand name drug. (A. 69).[11]

The majority then turned to the District Court's holding of "unprivileged imitation" and, after summarizing the relevant evidence, sustained that holding under both state and federal law on the ground that the trial judge's fact findings of nonfunctionality and secondary meaning were not clearly erroneous. Judge Higginbotham could not have been clearer that this was the basis for the Court's disposition:

> Judge Sarokin's finding of nonfunctionality is a finding of fact. A finding of fact is clearly erroneous when the reviewing court is left with the 'definite and firm conviction that a mistake has been committed.' [Citations omitted]. *We believe in this case appellant Bolar failed to prove that the district court's finding was clearly erroneous.*
>
> * * *

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11 Although the trial court had not "expressly recast" its preliminary injunction findings to conform with its grant of final relief, the Court of Appeals carried out that "mechanical task" in order "to ensure that the district court's conversion of its preliminary injunction does not become the basis of another appeal." (A. 64). Accordingly, the Third Circuit "treated the district court's findings that plaintiff has demonstrated 'likelihood of success' on the merits as findings that plaintiff 'succeeded' on the merits." (A. 66).

Based on this evidence *we cannot say that the district court's finding of non-functionality was clearly erroneous.*

* * *

[W]e turn to the final element [of a successful claim of unprivileged imitation]—*whether the district court's finding that the trade dress of APRESAZIDE capsules had acquired a secondary meaning was clearly erroneous.* The district court found that CIBA met its burden. *We agree.*

* * *

Because the district applied the correct legal standard [for secondary meaning], we must decide *only whether the district court's finding that APRESAZIDE patients identify those products with CIBA is clearly erroneous.* If we cannot say with firm conviction that its finding was clearly erroneous, we cannot reverse on this issue.

* * *

[W]e cannot say with firm conviction that a mistake was made by the district court in finding secondary meaning in APRESAZIDE's trade dress. *Because the district court's finding of secondary meaning was not clearly erroneous, it therefore must be upheld.*

* * *

To establish unprivileged imitation under the [Lanham] Act, a plaintiff must prove the nonfunctionality of the imitated feature and must prove secondary meaning of the imitated feature. These proofs are essentially the same as those required for unprivileged imitation under New Jersey law. [Citation omitted]. *Because the district court's findings of fact with respect to the New Jersey claim were not clearly erroneous, its findings of fact necessary to the proof of CIBA's federal claim were also not clearly erroneous.* (A. 71-73, 75, 79-80; emphasis added).

Turning to the District Court's *alternative* holding of "passing off," Judge Higginbotham first addressed the "requisite

proofs" for that tort under New Jersey law as "recently articulated"—that " 'it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form in which the manufacturer can reasonably anticipate that it may be passed off as another product. . . .' " (A. 76; citation omitted). Applying this *state* law standard to the record evidence, the majority sustained the District Court's finding that Bolar was guilty of "passing off" under New Jersey law:

> It was *not clearly erroneous* for the district court to find . . . that Bolar copied APRESAZIDE with the reasonable anticipation that pharmacists would illegally substitute Bolar's drug for CIBA's. (A.77; emphasis added).

With respect to the trial judge's *alternative* holding of "passing off" under federal law, Judge Higginbotham found that, while it was "debatable" whether *Ives* had jettisoned the "reasonable anticipation" standard in § 43(a) cases, it was "unnecessary" for the Court to decide that issue because the District Court's "factual findings and our review of them in this case *differ markedly* from the findings and their appellate review in *Ives*." (A. 80; emphasis added). As Judge Higginbotham elaborated:

> In contrast to the findings made by the trial judge exculpating the generic drug manufacturer [under § 32 of the Lanham Act] in *Ives, the findings made by the trial judge in this case implicate Bolar and constitute the prerequisite predicate for holding that there was a violation of section 43(a) of the Lanham Act.* Here, *inter alia*, the district court expressly found that Bolar's generic alternative could be mistaken for CIBA's APRESAZIDE, that many pharmacists had been convicted of illegal substitution in New York, that Bolar copied APRESAZIDE's trade dress with intent to increase sales of its generic alternative at the expense of CIBA, and that Bolar copied CIBA's trade dress with the intent, at least in part, to induce illegal substitution. Irrespective of the analysis

by the trial court as to the significance of footnote 13 in the *Ives* opinion, *on the basis of the record before us, we cannot say with definite and firm conviction that the trial court's finding of intent to facilitate illegal substitution was in error.* Just as the trial judge should not have been reversed by the Court of Appeals in *Ives, Judge Sarokin in this case, having had the opportunity to evaluate the credibility of witnesses and weigh the evidence, must be sustained on this issue because his findings are not clearly erroneous.* (A. 81-82; emphasis added).

Finally, the majority held that the District Court's "equitable finding concerning the public interest was not in error," noting that "[t]he evidence supports a finding that the practice of illegal substitution occurs and that its full extent cannot be shown." (A. 77-78). While Bolar's argument that it was in the public interest to copy APRESAZIDE's trade dress was "not necessarily frivolous," Judge Higginbotham concluded that "the district court could find, without being in error, that the greater damage to the public would result from the production of look-alike capsules." (A. 78 n.5).

As Judge Higginbotham correctly observed, the dissenting opinion—written by Judge Giles of the Eastern District of Pennsylvania—"devote[d] one-third of its discussion to an issue which [the majority] did not decide" (A. 83 n.10)—whether *Ives* overruled the "reasonable anticipation" standard for the tort of "passing off" under § 43(a) of the Lanham Act. (A. 83, 91-95).[12] Moreover, as to the ground on which the majority actually affirmed the District Court's "passing off" holding under § 43(a)—that it was not clearly erroneous for the trial judge to have found that Bolar had actually intended

12 Apparently realizing this, the dissent nevertheless believed it was desirable to resolve the issue in order to "provide necessary guidance to the lower courts within this Circuit." (A. 83). This, of course, would have been tantamount to giving an advisory opinion—a process in which the panel's majority correctly declined to engage. Nor did the full Court feel such "guidance" was necessary, since it subsequently denied rehearing *en banc*. (A. 105).

to induce illegal substitution—the dissent's sole disagreement was over the sufficiency of the evidence. In other words, Judge Giles would have held that "the district court's finding of intent to induce" was "clearly erroneous." (A.96).

Similarly, the dissent's sole disagreement with the majority over the District Court's "unprivileged imitation" holdings centered on the sufficiency of the evidence—and then only as it related to the element of secondary meaning. Indeed, Judge Giles explicitly "agree[d] with the majority's analysis and conclusions with respect to functionality," and acknowledged that the District Court had "articulated the appropriate legal standard for secondary meaning under both New Jersey and federal law. . . ." (A. 83-84). His view was simply that there was "insufficient evidence" to support a fact finding of secondary meaning. (A. 84).

Following the panel's affirmance, Bolar petitioned the Third Circuit for rehearing or rehearing *en banc*. On January 8, 1985, that petition was denied, "no judge who concurred in the decision having asked for rehearing, and a majority of the circuit judges in the circuit in regular active service not having voted for rehearing by the court in banc. . . ." (A. 105). Thereafter, Bolar filed the instant Petition.

REASONS FOR DENYING THE WRIT

I. The Sparing Exercise of This Court's Extraordinary Certiorari Jurisdiction Is Not Warranted to Determine Whether the Record Evidence Sufficiently Supported the District Court's Fact Findings Under the Clearly Erroneous Standard.

A. The Lower Court's Fact Findings With Respect to the Tort of "Unprivileged Imitation" Present No Conflict With This Court's Narrow Disposition in *Ives*.

Contrary to Bolar's contention (Petition at 9, 11, 18-30), the Third Circuit's affirmance of the District Court's "unprivileged imitation" holdings under state and federal law does not

"conflict" with this Court's limited disposition in *Ives* or with the Second Circuit's remand decision in that case—either with respect to nonfunctionality or secondary meaning, the two constituent elements of that tort.

Insofar as nonfunctionality is concerned, the difference in result between this case and *Ives* is attributable not to any conflict in legal standards, but solely to the fact that two trial judges, after evaluating the credibility of the witnesses and weighing the evidence before them, reached different factual conclusions with respect to the issue—hardly a matter which is worthy of certiorari. As for secondary meaning, this Court did not even address the issue in *Ives*, except in a passing footnote which the trial judge and the Court of Appeals here expressly took into account. The Third Circuit's holding that the trial judge's finding of secondary meaning was not clearly erroneous is simply another fact-bound determination which does not warrant the grant of certiorari.

1. Nonfunctionality

Contrary to Bolar's contention, the District Court did not "apply[ ] an improper legal standard for determining functionality. . . ." (Petition at 25). In fact, the trial judge quoted precisely the legal standard for functionality enunciated by this Court in *Ives* and, applying that standard to the evidence before him, found as a matter of fact that APRESAZIDE's trade dress was nonfunctional. (*See* A. 35). Nor did the Third Circuit apply an improper legal standard in affirming that fact finding as not being clearly erroneous. Indeed, even the dissenting judge expressly "agree[d] with the majority's analysis and conclusions with respect to functionality." (A. 84).[13]

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13 In *Ives*, this Court noted that "[i]n general terms, a product feature is functional if it is essential to the use or purpose of the article or if it affects the cost or quality of the article." (456 U.S. at 850 n.10). Applying that definition here, the District Court was plainly correct in finding APRESAZIDE's trade dress to be nonfunctional. As the trial judge found on the facts before him, APRESAZIDE's trade dress "ha[d] nothing to do with the purpose or performance of the drug, or with its processing" and that there was "no medical, pharmaceutical

As Judge Higginbothom noted below, any "assertion that *Ives* held that trade dress is functional as a matter of law is incorrect." (A. 79 n.7). The narrow issue resolved by this Court in *Ives* was whether the Second Circuit had exceeded the scope of its appellate review by reversing the trial court's holding that the defendants' duplication of the plaintiff's trade dress for its CYCLOSPASMOL product did not constitute contributory trademark infringement in violation of Section 32 of the Lanham Act, 15 U.S.C. § 1114. While the district court

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or manufacturing reason" that either had required CIBA to select the trade dress or had compelled Bolar to copy it. (A. 19-20, 35-36). Moreover, as the Court of Appeals noted, the record established that "generic equivalents to APRESAZIDE can be manufactured in different sizes, shapes or colors without added cost." (A. 77). Indeed, Bolar concedes that CIBA's choice of APRESAZIDE's trade dress was "arbitrary." (Petition at 5).

Nevertheless, Bolar argues that the District Court's functionality holding is at odds with "[a]nother common definition of functionality" which Bolar claims the Second Circuit used in *Ives*—that is, "[a] particular feature of an article is functional if it 'is an important ingredient in the commercial success of the product. . . .' " (Petition at 24). To begin with, that so-called test was not approved by this Court in *Ives*. Moreover, the Second Circuit itself has recently criticized the "commercial success" definition of functionality as "confusing" and "overinclusive," since "[t]rade dress associated with a product that has accumulated goodwill . . . will most always be 'an important ingredient' in the 'saleability' of the product." LeSportsac Inc. v. K Mart Corp., 754 F.2d 71, 77 (2d Cir. 1985); Warner Bros., Inc. v. Gay Toys, Inc., 724 F.2d 327, 330 (2d Cir. 1983). This dim view of the "commercial success" test is taken by other Circuits as well. *See, e.g.*, Sicilia Di R. Biebow & Co. v. Cox, 732 F.2d 417, 428 (5th Cir. 1984):

> To define functionality in terms of commercial success or marketing effectiveness . . . would permit a second comer to copy the distinctive dress of a product whenever it became successful and consumers became accustomed to its dress. [Citation omitted.] We do not doubt that such copying would enable the second comer to market his product more effectively, but the Lanham Act does not permit that result.

In effect, adoption of the "commercial success" test for functionality would make it impossible for a plaintiff ever to establish "unprivileged imitation," for proof of that tort's other element—secondary meaning—would *ipso facto* disprove nonfunctionality.

in *Ives* had also rejected plaintiff's § 43(a) claim on the facts before it, neither the Second Circuit nor this Court had reached that holding. (456 U.S. at 853, 858-59).

In deciding the § 32 issue in *Ives,* this Court noted that "[w]hile the doctrine of functionality is most directly related to the question of whether a defendant has violated § 43(a) of the Lanham Act"—the statutory provision relied upon here—"a finding of functionality may also be relevant to an action involving § 32," since it tends to indicate "a legitimate reason for producing an imitative product." (456 U.S. at 858 n.20). In that limited context, this Court held that the Second Circuit had committed reversible error by "substitut[ing] its interpretation of the evidence for that of the trial court" without first rejecting the District Court's fact finding of functionality as "clearly erroneous" under Rule 52(a). (*Id.* at 855, 857). As Justice O'Connor explained:

> The appellate court was not entitled simply to disregard the District Court's finding of functionality. . . . If the Court of Appeals disagreed with the District Court's factual findings, it should not have dismissed them without finding them clearly erroneous. (*Id.* at 858 n.20).

This Court's precise holding—that "[t]he Court of Appeals erred in setting aside *findings of fact* that were not clearly erroneous" (*id.* at 858; emphasis added)—puts the lie to any contention that *Ives* ruled that all drug trade dress is functional as a matter of law.[14]

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14 Indeed, this Court did not even view the trial court's factual finding of functionality in *Ives* as dispositive of plaintiff's § 43(a) claim. Instead, it remanded the case to the Second Circuit for an "independent review" of that claim. (456 U.S. at 858-59). Had the Court held that drug trade dress was functional as a matter of law, that remand would have been unnecessary. Nor did the Second Circuit on remand view this Court as holding that drug trade dress was functional as a matter of law. Rather, the Second Circuit affirmed the dismissal of plaintiff's § 43 claim on the basis of the trial judge's *factual* findings which the Second Circuit held could not be "label[ed] . . . clearly erroneous." (A. 59). In this connection, it is noteworthy that the

The critical distinction between this case and *Ives* is that here the Third Circuit *affirmed* a district court fact finding of nonfunctionality as not being clearly erroneous, whereas in *Ives* the Second Circuit *reversed* a fact finding of functionality without holding it clearly erroneous. Thus, the District Court correctly held that "[n]othing in *Ives* precludes this court from evaluating the relevant evidence and concluding that the trade dress here in issue is nonfunctional." (A. 39-40).[15]

Viewed properly, then, the only issue presented by Bolar with respect to functionality is whether the Third Circuit erred in affirming the District Court's fact finding of nonfunctionality as not being clearly erroneous—an issue that hardly merits the sparing exercise of this Court's certiorari jurisdiction. Indeed, in *Ives* itself, Justice White stated that "if the issue presented in the petitions for certiorari had been whether the clearly erroneous standard, although properly invoked, was erroneously applied, it is doubtful in my mind that this

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Second Circuit's remand opinion was "not published pursuant to Second Circuit Rule 0.23" (*see* A. 60)—which means that "each judge believe[d] that no jurisprudential purpose would be served" by such publication. (2d Cir. R. 0.23). If, in fact, the Second Circuit had read *Ives* to hold that all drug trade dress was functional as a matter of law, it surely would have been of sufficient "jurisprudential" import to have warranted the opinion's publication.

15 For the same reason, the Court of Appeals' affirmance in this case is not in conflict with the Second Circuit's remand decision in *Ives*. As already noted (*see* p. 16 n.14, *supra*), on remand in *Ives*, the Second Circuit simply affirmed the trial judge's fact findings as not being clearly erroneous, which is precisely what the Third Circuit did here. Thus, the difference in result in the two cases turned solely on the trial judges' different assessments of the facts before them, including issues of credibility. Nor is Bolar correct that "[t]he facts in this case are the same as the facts . . . in *Ives*." (Petition at 8). For example, in *Ives* there was evidence before the district judge that it was difficult to sell a non-look-alike version of CYCLOSPASMOL to hospitals, pharmacies and wholesalers and that, indeed, the defendant's parent had discontinued the sale of a non-look-alike product for that reason. (488 F. Supp. at 399). Here, in marked contrast, the record demonstrated that another pharmaceutical manufacturer was "successfully marketing" distinctly different-looking capsules "as generic alternatives" to APRESAZIDE and that Bolar could have done the same and secured a "strong market position." (A. 20, 48).

fact-bound issue would have warranted certiorari." (456 U.S. at 859). Justice White's skepticism reflects this Court's long-standing view that "[w]e do not grant certiorari to review evidence and discuss specific facts." *United States* v. *Johnston*, 268 U.S. 220, 227 (1925). As this Court's "repeated pronouncements" have made clear, "it 'cannot undertake to review concurrent findings of fact by two courts below in the absence of a very obvious and exceptional showing of error.' " *Berenyi* v. *Immigration Director*, 385 U.S. 630, 635 (1967), *quoting Graver Mfg. Co.* v. *Linde Co.*, 336 U.S. 271, 275 (1949). No such "obvious and exceptional" showing has been or could be made here given the ample evidentiary support for the District Court's nonfunctionality finding. (*See* A. 1924).

2. Secondary Meaning

As previously noted, in finding that APRESAZIDE's trade dress had achieved secondary meaning, the trial judge applied "the well-settled legal criteria for determining secondary meaning." (A. 24). Moreover, in affirming that factual finding as not being clearly erroneous, the Third Circuit held that "the district court applied the correct legal standard." (A. 73). Indeed, even a cursory review of the District Court's opinion demonstrates that the factors on which it relied in finding secondary meaning—including Bolar's intentional copying of APRESAZIDE's trade dress—are the very criteria that the courts throughout the Circuits have traditionally applied in determining this element of unprivileged imitation. (A. 24-25, 40-41).[16]

Nevertheless, Bolar contends that these traditional factors are "logically inapplicable" in the pharmaceutical industry and

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16 *See, e.g.*, Thompson Medical Co. v. Pfizer Inc., 753 F.2d 208, 217 (2d Cir. 1985); Ideal Toy Corp. v. Plawner Toy Mfg. Corp., 685 F.2d 78, 82 (3d Cir. 1982); Faberge, Inc. v. Saxony Prods., Inc., 605 F.2d 426, 428 (9th Cir. 1979); Truck Equip. Serv. Co. v. Fruehauf Corp., 536 F.2d 1210, 1220 & n.13 (8th Cir.), *cert. denied*, 429 U.S. 861 (1976). *See* J. McCarthy, *Trademarks & Unfair Competition* § 15.16 (1973); J. Gilson, *Trademark Protection & Practice* § 2.09[1] (1982).

should, in that context, be "rejected as a matter of law as proof of secondary meaning." (Petition 20, 22). Yet the facts in this case demonstrate the inappropriateness of any such hard and fast rule. For example, contrary to Bolar's contention, the District Court did not infer secondary meaning here based solely on the act of copying. Rather, the trial judge found that Bolar had copied APRESAZIDE's trade dress *without legitimate justification*—its "principal motivation" being to "increase sales" of its look-alike capsules at the "expense of [CIBA's] APRESAZIDE products" and to do so, at least in part, by inducing illegal substitution. (A. 18, 30, 46). In making those fact findings, the District Court rejected the testimony of Bolar's president that defendant had copied APRESAZIDE's trade dress for proper purposes—a matter of credibility uniquely within the trial judge's province. *See Anderson* v. *City of Bessemer*, 105 S. Ct. 1504, 1511-13 (1985). Moreover, unlike the defendants in *Ives*, Bolar could not rely on the functionality of APRESAZIDE's trade dress as "a legitimate reason for producing an imitative product" (456 U.S. at 857 n.20), since the trial judge found as a matter of fact that APRESAZIDE's trade dress was *non*functional. Thus, on this factual record—which is plainly distinguishable from *Ives*—the District Court was perfectly justified in inferring secondary meaning from Bolar's intentional copying, among other things.[17] Indeed, even the district judge in *Ives*, whom Bolar is so fond of quoting, did not rule as a matter of

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17 *Amicus* GPIA is thus wrong in asserting that the courts below held that "the mere act of copying" a product's appearance creates an irrebuttable presumption of secondary meaning that presents "the ultimate Catch-22" to a party who innocently copies a drug's trade dress. (GPIA Br. at 7). On the facts before him, the trial judge here rejected Bolar's claim of innocent motivation and the Third Circuit affirmed that rejection as not being clearly erroneous.

Moreover, the District Court did not infer secondary meaning solely from Bolar's non-innocent copying. For example, as the Court of Appeals pointed out, the District Court also "placed great significance in Bolar's 'consistent use of hydralazine hydrochloride/hydrochlorothiazide as the generic name of the product in suit . . . in finding that patients associate APRESAZIDE with one source." (A. 75).

law that secondary meaning could never be proven in a prescription drug case; he held only that, on the facts before him, the plaintiff there had failed to do so. (488 F. Supp. at 401).

In the final analysis, what Bolar is actually quibbling with is the District Court's assessment of the evidence with respect to secondary meaning, its factual findings with respect to that issue and the Third Circuit's affirmance of those findings as not being clearly erroneous. As we have already demonstrated with respect to nonfunctionality, those are plainly not matters which warrant this Court's review. (*See* pp. 14-18, *supra*). Given the ample evidentiary support for the District Court's finding of secondary meaning (A. 14-18, 24-28, 40-42), Bolar has not made, nor could it make, the "very obvious and exceptional showing of error" which is required before this Court will "undertake to review concurrent findings of fact by two courts below. . . ." *Berenyi* v. *Immigration Director, supra*, 385 U.S. at 635.

* * *

In sum, not only is there no conflict between *Ives* and the lower courts' findings with respect to the tort of "unprivileged imitation," but those findings—which alone are sufficient to support the judgment below—were eminently correct.

B. The Lower Courts' Fact Findings With Respect to the Alternative Tort of "Passing Off" Present No Conflict With This Court's Narrow Disposition in *Ives*.

Like Judge Giles' dissent below, Bolar's Petition devotes considerable attention to an issue which the Third Circuit majority expressly declined to decide—whether *Ives* overruled the "reasonable anticipation" test for the tort of passing off under § 43(a) of the Lanham Act. (Petition at 12-18). As previously noted, the Court of Appeals found it "unnecessary" to reach this "interesting theoretical" issue because the District Court's factual findings with respect to Bolar's intent—which "differ markedly from the findings" in *Ives*—

"implicate Bolar and constitute the prerequisite predicate" for a passing off violation under § 43(a) of the Lanham Act. (A. 80-81, 83 n.10). To grant certiorari to resolve an issue not reached by the Court of Appeals and "unnecessary" to its disposition would clearly violate this Court's venerable rule against rendering advisory opinions.

Bolar's sole response to the Third Circuit's *actual* holding is to argue that the District Court's finding that Bolar intended to induce illegal substitution was unsupported by the evidence and that, therefore, the Court of Appeals erred in not labeling it clearly erroneous. (Petition at 15-18). But, as this Court recently reiterated in *Anderson* v. *City of Bessemer, supra,* 105 S. Ct. at 1512, under Rule 52's "clearly erroneous" test:

> If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently. Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous.

Moreover, as Justice White went on to explain in *Anderson,* where a fact finding is "based on determinations regarding the credibility of witnesses"—as it was in this case with respect to Bolar's intent—"Rule 52 demands even greater deference to the trial court's findings; for only the trial judge can be aware of the variations in demeanor and the tone of voice that bear so heavily on the listener's understanding of and belief in what is said." (*Id.*)

In light of these guiding principles, there can be no doubt that the Court of Appeals correctly held that the District Court's intent finding was not clearly erroneous.[18] Clearly, that

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18 As this Court has held, the issue of intent "is a pure question of fact, subject to Rule 52's clearly-erroneous standard," *Pullman-Standard* v. *Swint*, 456 U.S. 273, 287-88 (1982), which "depend[s] peculiarly upon the credit given to witnesses by those who see and hear them." United States v. Yellow Cab Co., 338 U.S. 338, 341 (1949).

nding was "plausible in light of the record viewed in its ntirety." In brief, Bolar's president testified that Bolar's sales would be substantially greater if it copied APRESAZIDE's trade dress rather than marketing a non-look-alike generic version, and that Bolar's wholesale customers "prefer[red]" it to duplicate APRESAZIDE's trade dress in order to increase their sales. (R. 206-07, 218-20, 620-23). Given the undisputed testimony of Bolar's medical expert that patients invariably accept different-looking generic substitutes if proper medical and pharmaceutical procedure is followed (A. 22)—that is, if they are told that the generic equivalent is chemically and therapeutically identical—and the undisputed fact that another pharmaceutical manufacturer was "successfully marketing" a non-look-alike generic version of APRESAZIDE (A. 20), it was at least a "permissible view" of the evidence—if not the only plausible one—that Bolar intended that the substantial sales increase it expected from selling its product in a look-alike trade dress would be achieved through *illegal,* not legal, substitution. When coupled with the District Court's unique opportunity to evaluate the credibility of Bolar's president—whose testimony was impeached no fewer than *seven* times by his flatly inconsistent deposition testimony[19]—its finding of an intent to facilitate illegal substitution had more than sufficient evidentiary support to pass muster under Rule 52(a).[20]

Moreover, even if the Third Circuit had affirmed the District Court's § 43(a) "passing off" holding on the basis of the "reasonable anticipation" standard—which it expressly declined to do—there would still be no conflict with *Ives* because that case, unlike this one, did not involve a claim of "passing off" under § 43(a).

As already noted, this Court never reached plaintiff's § 43(a) claim in *Ives.* The reversal of the Second Circuit for failure to

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19 *See* A. 11; R. 188-90, 195-97, 204, 206-18, 221-25, 233-34, 262-66.

20 Bolar is thus wrong in arguing that the trial judge's "finding of intent to induce [was] based on nothing more than copying the appearance of a competitor's product. . . ." (Petition at 18).

comply with Rule 52's clearly erroneous standard was limited to plaintiff's claim of contributory trademark infringement under § 32 of the Lanham Act. Thus, this Court stated that "the judgment of the Court of Appeals that the petitioners violated § 32 of the Lanham Act is reversed." (456 U.S. at 858). In contrast, the case was remanded to the Second Circuit for an "independent review" of plaintiff's § 43(a) claim because—as this Court was at pains to note—that provision "prohibits a broader range of practices than § 32, as may the state unfair competition law. . . ." (*Id.*) Accordingly, *Ives'* purported rejection of the "reasonable anticipation" standard was confined, on its face, to § 32 claims of contributory trademark infringement.

In applying the "reasonable anticipation" standard for the tort of passing off under § 43(a), the District Court followed the lead of *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, Inc.*, 625 F.2d 1055 (3d Cir. 1980), where the Third Circuit gave concretion to *Ives'* statement that that provision outlaws a "broader range" of conduct than does § 32. There, citing Judge Hastie's "leading" opinion in *L'Aiglon Apparel, Inc.* v. *Lana Lobell, Inc.*, 214 F.2d 649 (3d Cir. 1954), the Third Circuit explained that "[i]t is well established that Section 43(a) proscribes not only acts that would technically qualify as trademark infringement, but also unfair competitive practices involving actual or potential deception," including the tort of passing off. (625 F.2d at 1065). Because of that "broader" reach, the "reasonable anticipation" standard promotes § 43(a)'s purposes. For, as the District Court reasoned:

> By putting in the hands of pharmacists, through intermediate wholesalers and distributors, a product which admittedly will facilitate illegal passing off, Bolar knowingly creates a real potential for deception, whether or not it is technically guilty of contributory trademark infringement. (A. 46).

What is more, even if *Ives* overruled the "reasonable anticipation" standard for the tort of "passing off" under § 43(a),

and even if the Third Circuit had affirmed the District Court's "passing off" holding under § 43(a) on the basis of that standard, the fact remains that the District Court held *alternatively* that Bolar was guilty of passing off under New Jersey state law, and the Third Circuit affirmed that alternative holding and the full Court denied rehearing *en banc*. (A. 44-47, 76-77, 105). Nor is the Court of Appeals' interpretation of New Jersey law worthy of certiorari review. As this Court declared in *Huddleston* v. *Dwyer,* 322 U.S. 232, 237 (1944), "ordinarily we accept and therefore do not review, save in exceptional cases, the considered determination of questions of state law by the intermediate federal appellate courts." *Accord, Estate of Spiegel* v. *Commissioner,* 335 U.S. 701, 707-08 (1949).[21]

Finally, and apart from all else, it would be improvident for this Court to grant certiorari to review the District Court's "passing off" holdings under federal and state law *unless* it were also prepared to conclude that the District Court's alternative holdings with respect to "unprivileged imitation" under federal and state law merited certiorari review. For otherwise the Court would be violating its long-standing rule against advisory opinions, since those alternative holdings provide an independently sufficient basis to support the judgment below.

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21 Bolar's contention (Petition at 17-18) that the Third Circuit's interpretation of New Jersey law "violate[s]" this Court's holdings in *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964), is without merit. Indeed, the Second Circuit in *Ives* explicitly rejected the argument that *Sears* and *Compco* preclude trade dress protection under state laws of unfair competition. Ives Laboratories, Inc. v. Darby Drug Co., 601 F.2d 631, 639-44 (2d Cir. 1979). *Accord,* SK&F, Co. v. Premo Pharmaceutical Laboratories, Inc., 625 F.2d 1055, 1064-65 (3d Cir. 1980); Dallas Cowboys Cheerleaders, Inc. v. Pussycat Cinema, Ltd., 604 F.2d 200, 203-04 (2d Cir. 1979).

II. Bolar's Purported Public Policy Arguments Are Misplaced and Provide No Basis for the Grant of Certiorari.

Bolar's contention that the judgment below "inhibits the national policy in favor of free competition" and is thus "anti-competitive" (Petition at 30-32) proceeds from the false premise that conduct which constitutes *unfair* competition under federal and state law cannot be proscribed. If that were true, this Court in *Ives* would not have remanded plaintiff's federal and state unfair competition claims for the Second Circuit's "independent[ ] review" (456 U.S. at 858-59); it would simply have held—as the petitioners in that case likewise argued—that "the national policy in favor of free competition" prohibited an injunction against the duplication of a prescription drug's trade dress.

In fact, contrary to Bolar's contention, there is no inconsistency between the interdiction of *unfair* methods of competition and the "national policy in favor of free competition." As the Third Circuit aptly put it in *SK&F, Co.* v. *Premo Pharmaceutical Laboratories, supra,* 625 F.2d at 1067:

> The public policy of both the United States and New Jersey favors free and open competition. But Congress in Section 43(a) of the Lanham Act and New Jersey in its common law of unfair competition have recognized that certain kinds of business activity, while promoting competition in the short run, are in the long run apt to be destructive of competition. The adoption of a distinctive trade dress as a means of identifying a product with its source is a legitimate means for the promotion of the user's business, and permitting piracy of that identifying trade dress can only discourage other manufacturers from making a similar individual promotional effort. Moreover, allowing a manufacturer to be able to acquire and maintain a reputation for consistent good quality is certainly procompetitive. . . . But even if the Lanham Act and the New Jersey law of unfair competition were not in

> the long range interests of competition, preventing deception of the public is itself in the public interest.

Moreover, the injunction granted in this case in no way creates an "artificial barrier" to *legitimate* competition. (Petition at 32). To the contrary, Bolar is entirely free to make and market its generic version of APRESAZIDE in distinctly different-colored capsules and to compete with CIBA's products on the merits—in terms of price, quality and reputation—without appropriating APRESAZIDE's trade dress. As the District Court explicitly found:

> Like Reid-Provident, Bolar could have begun marketing its hydralazine hydrochloride/hydrochlorothiazide combinations in March 1982 in differently colored capsules than APRESAZIDE, if not tablet form, and achieved the same strong market position which it admits Reid-Provident has achieved. (A. 48).

Nor, contrary to Bolar's contention, is the public policy underlying generic drug substitution laws in any way offended by the enforcement of CIBA's federal and state rights against Bolar's unfair competition. For as one court has perceptively explained:

> [T]he raison d'etre of generic substitution laws is to give consumers equivalent pharmaceutical products at lower prices. Consumers who unknowingly receive a generic but pay brand name prices do not derive any of the benefits of the generic substitution laws. Simulation of Persantine's trade dress renders this deprivation of intended benefits possible.

Boehringer Ingelheim G.m.b.H. v. *Pharmadyne Laboratories*, 532 F. Supp. 1040, 1067 (D.N.J. 1980) (Lacey, J.).[22]

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22 Similarly, in construing New York's generic substitution law, that state's highest court unanimously stated:

> The "Generic Drug Substitution Law" does not promote unfair competition or the infringement of drug patents or trade-marks;

Finally, *amicus* GPIA incorrectly asserts that a patient's right to "informed consent"—which the District Court invoked in support of its injunction—"has no identifiable counterpart in the state or federal laws of unfair competition. . . ." (GPIA Br. at 4). In fact, in enacting the Lanham Act, Congress made it clear that protection of a consumer's informed "choice between competing articles" was at the heart of the statute, and that trademarks promote that objective by "enabling the buyer to distinguish one [competing article] from the other."[23] Indeed, this Court has explicitly recognized the right of "informed consent" which GPIA contends does not exist:

> If consumers or dealers prefer to purchase a given article because it was made by a particular manufacturer or class of manufacturers, they have a right to do so, and this right cannot be satisfied by imposing upon them an exactly similar article, or one equally as good, but having a different origin.

F.T.C. v. *Colgate-Palmolive Co.*, 380 U.S. 374, 388 (1965), *quoting F.T.C.* v. *Royal Milling Co.*, 288 U.S. 212, 216 (1933).[24]

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nor does the Law create any defenses to such claims. . . . [P]laintiff's rights and remedies under the patent and trade-mark laws are the same now as they were prior to the passage of the law.

Pharmaceutical Manufacturers Association v. Whalen, 54 N.Y.2d 486, 495, 446 N.Y.S.2d 217, 220-21, 430 N.E.2d 1270, 1273-74 (1981).

Justice White's reliance on state generic substitution laws in his concurrence in *Ives* was predicated on a district court fact finding that CYCLOSPASMOL's trade dress was functional. (456 U.S. at 861-62). Here, in contrast, the trial judge found as a matter of fact that APRESAZIDE's trade dress was nonfunctional—a fact finding which the Third Circuit held was not clearly erroneous.

23 S. Rep. No. 1333, 79th Cong., 2d Sess., *reprinted in* U.S. Code Cong. Serv. at p. 1275 (1946).

24 GPIA's absurd contention that patients do not care about the source of their medication (GPIA Br. at 12) is contradicted by the District Court's finding below that when patients are given a choice between a brand name drug and a generic equivalent they often choose to remain with the brand name medication (A. 21-22)—a finding supported by the testimony of Bolar's own medical and pharmacy experts. (R. 509,

CONCLUSION

For all the foregoing reasons, it is respectfully submitted that the Petition should be denied.

Dated: May 8, 1985

Respectfully submitted,

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583, 586, 588). Equally absurd is GPIA's claim that the District Court's reliance on informed consent "is an unwarranted attempt at judicial legislation to supplement the State substitution laws." (GPIA Br. at 4). In fact, state substitution laws like Illinois' *require* informed consent before permitting generic substitution. (A. 23 n.7).

PROOF OF SERVICE

I, Randolph S. Sherman, attorney for Respondent herein, and a member of the Bar of the Supreme Court of the United States, do hereby certify that on the 8th day of May 1985, I caused to be served by hand three copies of the foregoing Brief for Respondent CIBA-GEIGY Corporation in Opposition to Petition for Writ of Certiorari on Robert V. Marrow, Salon, Marrow, Dyckman & Trager, 41 East 42nd Street, New York, New York 10017. I further certify that all parties required to be served have been served.

Dated: May 8, 1985

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In The

Supreme Court of the United States

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

CIBA-GEIGY CORPORATION,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION AS *AMICUS CURIAE*

IN SUPPORT OF REVERSAL

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No.

In The

Supreme Court of the United States

October Term, 1984

BOLAR PHARMACEUTICAL CO., INC.,

Petitioner,

vs.

CIBA-GEIGY CORPORATION,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL INDUSTRY ASSOCIATION AS *AMICUS CURIAE*

PRELIMINARY STATEMENT

This Amicus Brief is presented by the Generic Pharmaceutical Industry Association pursuant to Rule 36.1 of the Supreme Court Rules with the written consent of both parties on file with the Clerk of this Court. This brief supports the petition of Bolar Pharmaceutical Co., Inc. that a writ of certiorari issue to review the decision of the Court of Appeals for the Third Circuit.

INTEREST OF AMICUS CURIAE

The Generic Pharmaceutical Industry Association was formed in 1980 by a group of independent generic drug manufacturers,

distributors and retailers to seek solutions to common problems having an economic impact on the distribution and sale of generic drugs. Many of these problems relate to the implementation of the laws enacted in all 50 States, the District of Columbia and Puerto Rico, which are intended to encourage the substitution of lower cost, therapeutically equivalent, generic drugs for unpatented high priced, heavily promoted brand name drugs as a means of reducing health care costs. The Association's member companies account for a substantial portion of the sales of independently manufactured generic prescription drugs.

The questions raised in this case transcend the specific petitioner and facts and have a direct economic impact on the generic pharmaceutical industry, government medical reimbursement programs and consumers of prescription drugs. Prior to the decision below and similar recent decisions in the Third Circuit, a long line of precedents had held that the size, color and shape of prescription drugs were functional because those appearance features helped patients to identify the medication and, therefore, could not be the exclusive property of a single manufacturer. Dozens of identically colored drugs made by different manufacturers had, in fact, coexisted in the marketplace for many years without engendering any legal controversy. This Court's decision in the *Ives*[1] case, although not directly addressing all of the relevant legal issues, was generally supportive of the sale of generic equivalent drugs which look like the brand name drug which the patient was accustomed to taking. The Second Circuit's ultimate decision on remand in the *Ives* case affirmed a district court decision permitting the sale of a generic drug which was identical to a brand name drug in appearance. The facts in that case are indistinguishable from this case and the dissent below mirrors the opinion of the district court in the *Ives* case.

The conflict between the decisions in the Second and Third Circuits has created a new game in which generic drug companies are forced to seek declaratory judgment relief in the Second Circuit before they are sued in the Third Circuit. The victims of this game are the members of Amicus who are unable to make rational

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1. *Inwood Laboratories v. Ives Laboratories, Inc*. 456 U.S. 844 (1982).

business judgments due to the uncertainty as to which Court will ultimately decide a particular case. Unless this Court settles these issues by establishing a uniform legal standard, the Third Circuit's decisions will force the generic drug industry to abandon the practice of manufacturing generically equivalent drugs in the identifying colors with which the patient is familiar. The real losers will be the sick and the aged who will be deprived of the primary means by which they identify their medications. The economic, health and safety implications of that deprivation are staggering, and it should not be permitted to occur without a full hearing in this Court.

SUMMARY OF ARGUMENT

The basic question raised by all of the drug appearance cases is: What does the capsule or tablet appearance actually mean to patients? If patients associate the appearance of a product with a particular manufacturer of the medication, then it serves the same function as a trademark and should be protected. But, if patients rely on tablet appearance to identify the medication itself, rather than a particular manufacturer, all FDA approved, equivalent medications should be entitled to have the same appearance. That conclusion is consistent with a series of decisions by this Court spanning almost one hundred years.[2]

The District Court opinion below contains an unequivocal finding that patients rely on the appearance of prescription drugs to identify the medication and not to identify a source of origin. Judge Sarokin found that, when a patient who has previously been taking a brand name product receives a different looking generic equivalent,

> " . . .the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed."

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2. *Singer Mfg. Co. v. June Mfg. Co.*, 163 U.S. 169 (1896); *Warner & Co. v. Eli Lilly & Co.*, 265 U.S. 526 (1924); *Kellogg Co. v. National Biscuit Co.*, 305 U.S. 111, 83 L.Ed. 73 (1938); *Sears Roebuck & Co. v. Stiffel Co.*, 376 U.S. 11 L. Ed. 2d 661, 84 S. Ct. 784 (1964); *Compco Corp. v. Day-Brite Lighting, Inc.*, 376 U.S. 234, 11 L. Ed. 2d 669, 84 S. Ct. 779 (1964); and *Inwood Laboratories, Inc. v. Ives Laboratories, Inc.*, 456 U.S. 844, 72 L.Ed. 2d 606, 102 S.Ct. 2182 (1982).

That finding establishes that drug appearance features identify the medicine, and not its source. It should have resulted in an immediate dismissal of all of Ciba's claims. Instead, Judge Sarokin found that the "fears and anxieties" of patients, arising from the belief that the wrong medication had been dispensed, would be quelled once the pharmacist provided an explanation and that such an explanation was necessary so that the patient could exercise "informed consent" to generic substitution. The concept of "informed consent" has no identifiable counterpart in the state or federal laws of unfair competition and is an unwarranted attempt at judicial legislation to supplement the State substitution laws.[3]

In *Ives,* this Court rejected the notion that a "watering down" of the standards for determining contributory infringement was an appropriate solution to any problem relating to illegal substitution. The watering down of the standards for determining secondary meaning is equally repugnant. It makes no sense to find that the appearance of a drug product has acquired secondary meaning based on inferences drawn from advertising which never reaches the patient and presumptions from the fact that the product appearance was copied, when the direct evidence of the patient's state of mind establishes that the appearance features identify the medicine and not the manufacturer. Yet, that is precisely what the lower courts did in this case.

Ironically, the state substitution laws were enacted because the manner in which prescription pharmaceuticals were previously dispensed left the consumer with no choice whatsoever in the selection of the source of its drug products. Those laws reflect a belief by the states that the persistent use of the brand name as though it was the generic name for a drug during the period of patent exclusivity directly contributes to inordinately high drug prices after expiration of the patent monopoly. The substitution laws represent state action in aid of the welfare of its citizens

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3. This Court has made it clear that states are in a position to ensure that pharmacists meet high standards of integrity or lose their licenses to practice. *Virginia State Board of Pharmacy v. Virginia Citizens' Consumer Council, Inc.,* 425 U.S. 748, 48 L. Ed. 2d 346, 96 S. Ct. 1817 (1976). There is no need for the courts to rewrite existing statutes, and no authority for them to do so.

which should have been given full respect by the Third Circuit, absent any conflicting and overriding federal law which mandated a contrary result. This Court has previously recognized the need to avoid judicial decisions which force the poor and the aged to choose between the alleviation of pain and the enjoyment of basic necessities.[4] It should not force consumers to live with even a moment of fear and anxiety about their medications as the price for buying a lower cost generic drug.

It is also evident that the Third Circuit watered down, if not outright ignored, this Court's rejection of "reasonable anticipation" as a proper test for determining whether a generic drug manufacturer is liable for illegal substitution at the retail level. The doctrine of contributory infringement restated by this Court in *Ives* stems from basic principles of unfair competition law which existed for many years under the common law and remain constant, irrespective of whether the issue is presented under Section 32 or Section 43(a) of the Lanham Act. Those principles preempt any contrary interpretation of state law.

ARGUMENT

I.

The Third Circuit applied an erroneous legal standard in holding that appearance features had secondary meaning and were not functional.

The courts below correctly stated that to succeed on a claim of unprivileged imitation either under the common law, or under Section 43(a) of the Lanham Act, it must be established that the appearance features for which injunctive relief is sought have (1) acquired secondary meaning and (2) are not functional. These prerequisites have been established by a century of consistent holdings by this Court[5] which recognize that imitation is the lifeblood of competition and that unhindered duplication of products must be permitted subject only to such limitations as are necessary to prevent consumer confusion with respect to the

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4. *Virginia State Board of Pharmacy, supra.*

5. *See* Footnote 2.

source of origin of products. Accordingly, the pink color of Pepto-Bismol[6] and the brown color of Coca-Cola[7] were not protected against copying since these features were associated in the mind of the public with the product itself and do not serve to identify any particular producer. Indeed, until the recent group of decisions barring generic drug manufacturers from selling identically colored pharmaceutical capsules, the cases dealing with drug products uniformly rejected attempts to enjoin a competitor from the use of the same color, even in instances where there was evidence to establish acts amounting to wrongful substitution or passing off at the consumer level. *Warner & Co. v. Lilly & Co., supra; Norwich Pharmacal v. Sterling Drug, Inc.*, 271 F.2d 569 (2d Cir. 1959), *cert. denied*, 362 U.S. 919 (1960); *Upjohn Co. v. Schwartz*, 246 F.2d 254 (2d Cir. 1957); *Smith, Klein & French Laboratories v. Clark & Clark*, 157 F.2d 725 (3rd Cir. 1946); *Marion Laboratories, Inc. v. Michigan Pharmacal Corp.*, 388 F.Supp. 762 (E.D. Mich. 1972).[8]

It is self-evident from the foregoing decisions that the burden is on the party asserting rights in the appearance of a product to establish the consumer's state of mind, *i.e.*, to establish that a product appearance feature has secondary meaning because it signifies a source of origin to the consumer. Recent cases recognize that the only truly meaningful way of satisfying the burden of proving consumer attitudes is to undertake a survey of consumer

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6. *Norwich Pharmacal Co. v. Sterling Drug, Inc.*, 271 F. 2d 569 (2d Cir. 1959).

7. *Coca-Cola v. Koke Co.*, 254 U.S. 143, 65 L. Ed. 189 (1920); *Coca Cola v. Snow Crest Beverages, Inc.*, 64 F. Supp. 980 (D. Mass. 1946), *aff'd* 162 F. 2d 280 (lst Cir.), *cert. denied* 322 U.S. 809 (1947).

8. The only pharmaceutical product cases found in which the appearance of the product was actually enjoined are the Dexadrine cases, *Ross-Whitney Corp., et al. v. Smith, Klein & French Laboratories*, 207 F. 2d 190 (9th Cir. 1953); *Smith, Klein & French Laboratories v. Brouder*, 125 U.S.P.Q. 299 (S.D. Tex. 1959). However, both of those cases involved a unique pill shape in addition to color.

reaction to the products under actual market conditions.[9] No such surveys were conducted in this case. Instead, the trial court improperly shifted the burden of proving the absence of secondary meaning to the generic manufacturer based on the clearly erroneous legal presumption that the act of copying the product appearance constitutes proof of secondary meaning. That presumption is the ultimate Catch-22 since a party who copies a product appearance in the belief that consumers associate that appearance with the product itself, and not with any particular manufacturer, will, by the mere act of copying, create a contrary presumption. This Court in *Ives* recognized that the functionality of capsule colors could provide at least one legitimate reason for producing an imitative product. In any event, this case does not involve the copying of arbitrary packaging features in a situation where consumers may be unfairly confused by adjacently displayed products at the point of purchase. In that environment, where the consumer must select a product, there may be some justification for a presumption based on simulation of appearance. In this case, the patient does not even see the product before it is purchased, and its appearance plays no role in product selection.

There is, of course, no legitimate or compelling reason to assume that the color of a prescription drug product is likely to designate a source of origin. To the contrary, if appearance was truly intended to designate the origin of a drug product, it would obviously make more sense for each company to use the same color for all of its products rather than to use a different color for each medication and even for each dosage of the same medication. Nor would there be any reason to include a Product Identification Section in the industry sponsored Physicians' Desk

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9. Some recent decisions have drawn negative inferences from the failure of a party to conduct such surveys where it had the financial means to do so. *Mushroom Makers, Inc. v. R. G. Barry Corp.*, 441 F. Supp. 1220, 1231 (S.D.N.Y. 1977) *aff'd*, 580 F. 2d 44 (2d Cir. 1978) *cert. denied*, 439 U.S. 116 (1979); *Information Clearing House v. Find Magazine*, 492 F. Supp. 147, 160 (S.D.N.Y. 1980); McCarthy, *Trademarks and Unfair Competition*, Section 12:1 (pp. 405-6).

Reference which includes color photographs to help doctors identify each drug.[10] These telltale signs of the functionality of drug colors cannot be swept away on the irrelevant ground that the initial color selection was arbitrary and any color could have been used, although that is precisely the position taken in the recent decisions of the Third Circuit. It seems highly unlikely that the same logic would be applied to a traffic light or a fire engine although the initial selection of their colors was also a matter of arbitrary choice.

The decisions below also erroneously rely on evidence of extensive sales and advertising to support the claim that capsule appearance has secondary meaning to consumers. The underlying rationale for considering such circumstantial evidence is an inference that widespread advertising and exposure of a product feature to a substantial number of people in the relevant buyer class will eventually create in the buyer's mind an association between that feature and a single source. While a seller's efforts to expose buyers to product appearance may be relevant evidence from which secondary meaning may be inferred in some cases, such efforts do not automatically lead to an irrebuttable presumption that advertising or sales have been effective in creating secondary meaning. The test of secondary meaning is the effectiveness, not the extensiveness, of the effort to create it. *Aloe Creme Laboratories, Inc. v. Milsan, Inc.*, 423 F.2d 845 (5th Cir. 1970); *Carter-Wallace, Inc. v. Procter & Gamble Co.*, 434 F.2d 794 (9th Cir. 1970). The mere fact that a particular product is popular and enjoys a dominant market position also does not establish that the public associates the product appearance with a particular source. *Norwich Pharmacal v. Sterling Drug, Inc.; supra; Application of Deister Concentrator Co.*, 289 F.2d 496

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10. In the introduction to *The Pill Book*, Bantam Books (1982), Dr. Frank Field, the well-known television science commentator states: "Think of the value of accurate, life-sized color pictures of pills if, for example, you are in an emergency situation with an elderly relative where various pills are mixed together in an unmarked pillbox." There are over one million copies of *The Pill Book* in print and this statement concerning the functionality of color cannot be lightly disregarded.

(C.C.P.A. 1961); *Application of Honeywell, Inc.*, 532 F.2d 180 (C.C.P.A. 1976).

The unique circumstances under which prescription drugs are marketed actually eliminates any basis for an inference that patients will associate the appearance of a capsule with a single source of origin rather than with the medication itself. All of the massive advertising and promotion by the brand name manufacturers is directed at physicians and pharmacists, and no advertising of any kind is ever directed at consumers. Thus, the only information in the patient's possession is the information on the prescription vial and on the pill itself. That information does not inform the patient that the color or shape of the pill is a trademark and that all pills with that name and appearance are made by a single producer. Indeed, patients taking a drug are often switched from one dose to another and are exposed to a different color each time there is a change in their medication.[11] The logical inference, if inferences are to be drawn at all, is that color was intended to convey information about the medicine. As stated in *Bayer Co., Inc. v. United Drug Co.*, 272 F. 505 (S.D.N.Y. 1921)

> "The plaintiff argues that . . .it is impossible to get a trade-mark for an 'ethical' remedy, which apparently means a remedy not directly advertised or sold to the public. But it must not blow hot and cold. If a manufacturer thinks it undesirable to advertise and sell drugs direct, the inevitable con sequence of adhering to that standard is that no trade-mark among consumers can be acquired, because they can know nothing of it." 272 F. at 512.

With these words, Judge Learned Hand held that the word "Aspirin" identified a medication and not a source of origin. Clearly, he would have had a much easier time in reaching the

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11. The Ciba drug involved in this action is sold in three different dosage strengths and each dosage has its own color.

same conclusion with respect to appearance features which, by their very nature, would be less likely to have trademark significance to consumers than the name of the product.[12]

The undisputed findings of the District Court below (which were never even mentioned by the Third Circuit in its opinion) dramatically serve to demonstrate the legal impropriety of substituting presumptions and inferences concerning secondary meaning for direct proof of the consumer's state of mind. Judge Sarokin held that when a patient already on a brand name drug receives a prescription containing a different looking generic equivalent drug " . . .the patient will usually call his physician or pharmacist to inquire whether the correct medication has been dispensed." (App. 22). Indeed, the District Court also acknowledged that the uncertainty created by the differences in appearance would cause the typical patient to suffer some anxiety. Judge Sarokin failed to give that uncontradicted finding any weight with respect to the secondary meaning and functionality issues. Instead, he relied on expert testimony which established that the patient's initial anxiety would be quelled after the physician or pharmacist explained to the patient that different colors signify different manufacturers rather than different medicines. In finding that an explanation to the patient was essential to clear up the patient's belief that the wrong medicine had been dispensed, Judge Sarokin stated (App. 22):

> "If the fears and anxieties of the patient could not be quelled by such an explanation, it may well be that a finding of functionality would be mandated."

It apparently never occurred to Judge Sarokin that if patients actually believed that the appearance of a drug product identified its source, they would not need the explanation! The need for

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12. Both the dissent below and Judge Nickerson's Opinion in *Ives Laboratories v. Darby Drug Co., Inc.*, 488 F. Supp. 394 (E.D.N.Y) expressly rejected the notion that extensive advertising to physicians and pharmacists would or could have any bearing on whether product appearance features had secondary meaning to consumers.

an explanation is the ultimate proof that tablet appearance is functional because it aids the patient in confirming that the correct medication is dispensed. It is also the ultimate proof that drug colors do not have secondary meaning.[13]

Judge Sarokin's opinion is silent with regard to such questions as the circumstances under which the patient will first discover that a different colored medication was dispensed; the length of time which will elapse until the patient can receive the essential explanation; the dangers caused by the patient's failure to take essential medication during the intervening period; and the cost to physicians and pharmacists in taking the time necessary for such explanations. It is naive to believe that patients actually open prescription vials in the drug store to check the color of the pills. Clearly, the foregoing factors will combine to provide Ciba and other brand name manufacturers with a competitive advantage over a generic drug having a different appearance. This Court has repeatedly held that the purpose of the laws relating to unfair competition is to prevent confusion among consumers and to promote competition between manufacturers. In contrast, the Third Circuit's decision in this case creates confusion and anxiety for patients and an unfair competitive advantage for brand name manufacturers.

II.

The lower court's attempt to mandate product appearance differences for the purpose of "informed consent" is unsupported as a matter of law or policy.

Judge Sarokin's failure to recognize that the "fears and anxieties" of patients mandated a finding that the tablet

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13. No one disputes that patients can be re-educated when provided with an explanation by physicians and pharmacists. But it is not the job of these health care professionals to create secondary meaning where none exists. According to the decisions below, Ciba's extensive sales and advertising had allegedly already delivered the proper message to consumers concerning the significance of appearance features. Obviously, if an explanation is still needed, the message was never received.

appearance was functional and had no secondary meaning was due to his well-intentioned, but misguided, belief that generic drugs should have a different appearance so that patients could exercise "informed consent" to any change in the source of their medicines. The concept of "informed consent" is clearly not part of any statutory or common law doctrine of unfair competition. Rather, it is an unwarranted attempt by the courts in the Third Circuit to legislate social policy and to interfere with the intended implementation of state substitution laws.

The courts below clearly disregarded the unique marketing environment of prescription pharmaceuticals and failed to differentiate this case from an everyday shopping situation in which the consumer's purchasing decision may be unfairly influenced by too close a similarity in appearance of adjacently displayed products. Here, as a Federal Trade Commission study has aptly noted, the physician prescribes, the pharmacist dispenses, and the patient pays.[14] As previously noted, no advertising or promotional activities are directed at patients, and prescription drugs are not purchased by choice or on impulse. The average patient neither knows nor cares if the name or appearance of a medication is associated with a single producer. The patients care only that they receive the medication which their doctor prescribed and that it works for the purpose intended. The state substitution laws are, in essence, nothing more than a recognition of these facts and the overriding fact that brand name prescription practices had totally deprived patients of any choice in the source of their medications, thereby causing unfairly high drug prices.

During the 1950's and 60's most states had in place "anti-substitution" laws which prohibited the pharmacist from dispensing any product other than the product specificially identified on the prescription.[15] These laws were originally intended

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14. Staff Report to the Federal Trade Commission, Drug Product Selection 96 (1979).

15. FTC Staff Report, *supra*, Note 14 at 146, *et seq.* The FTC Staff Report contains a thoroughly documented analysis of the role of the manufacturer, (Cont'd)

to prevent pharmacists from dispensing unsafe products, but they also provided significant economic impetus for major pharmaceutical companies to use promotional techniques designed to encourage brand name prescribing by physicians.

In 1962, Congress amended the Food, Drug and Cosmetic Act to include provisions requiring manufacturers of new drugs to establish, prior to marketing, that those drugs were safe and effective. *See* 21 U.S.C. §321, *et seq.* The FDA also established a code of good manufacturing practices to ensure that all products were not only identical in their composition and therapeutic value, but were also safely manufactured.

By the late 1960's, it had become apparent that the amendments to the Food and Drug law were working in a manner which assured that approved generic drugs were equivalent to their brand name counterparts, and this fact was publicly expressed by the regulatory experts at the FDA on numerous occasions.[16] This established equivalence of generic drugs to their brand name counterparts should logically have led to a rapid expansion in the rate of sale of those products in view of their significantly lower cost to consumers. Numerous reported studies over the past ten years have documented the significantly lower cost of generic drugs and the savings which are realized on generic drug purchases.[17]

(Cont'd)

physician, pharmacist, patient and State and Federal regulation in the distribution and selection of prescription drugs and the impact of these factors on competition.

16. *See,* for example, FDA Consumer Magazine, March 1973; FDA Consumer Magazine, February 1978.

17. FTC Staff Report, *supra,* Footnote 14 at 196-219; this Court has taken notice of studies establishing price differentials of up to 1200% for the same amount of a specific drug and concluded that "the phenomenon of widely varying drug prices is apparently national in scope." *Virginia State Board of Pharmacy v. Virginia Citizens Consumer Council, Inc., supra,* at 754; Consumer Reports, January 1975, at page 48.

Despite the enormous price differentials, generic pharmaceutical products account for only a small share of the prescription pharmaceutical market. There can be no doubt that the use of the brand name as if it were the generic name and the state anti-substitution laws were responsible for that result. During the ten year period from 1968 to 1977, only 10% to 14% of all new prescriptions were written by physicians using the generic name of the medication, and that figure is inflated by a higher percentage of generic prescriptions for certain antibiotics.[18]

It was against this backdrop, that the states, acting to protect the health and welfare of their citizens, modified the anti-substitution laws and enacted laws which encouraged the substitution of lower-cost, therapeutically equivalent drugs for the brand name product actually set forth on a prescription.[19] It should be painfully obvious in view of the foregoing history that the assertion that the appearance of tablets and capsules is protectable trade dress, *i.e.*, functions as a trademark, amounts to nothing more than an attempt by Ciba and other brand name companies to erect a new barrier to the dispensing of lower-costing, generic equivalent drugs to replace the brand name barrier which was torn down by the state substitution laws. Such a barrier cannot be justified under the guise of "informed consent" even if, for the sake of argument, the concept of "informed consent" is valid. Product appearance differentiation is neither necessary nor desirable as a means of establishing such consent.

Although the mechanics of the state substitution laws vary from state to state, they are all based on a common principle, namely, that the use of a brand name on a prescription written by the doctor does not automatically mean that the brand name product will be dispensed. Depending upon the requirements of

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18. Annual Prescription Survey by The Albany College of Pharmacy, Medical Marketing and Media, April 1978 at 24; Multi-Source Drugs: An Acceleration in the Use of Lower-Costing Substitutes? Reynolds Securities Information Report, May 13, 1977.

19. *Pharmaceutical Society of NY Inc. v. Lefkowitz*, 454 F. Supp. 1175 (S.D.N.Y. 1978), *aff'd* 586 F.2d 953 (2d Cir. 1978).

a particular state, the physician must give some further indication that the use of the brand name was actually intended to command the pharmacist to dispense the brand name product and was not merely being used as a means of describing a type of medication. The New York substitution law[20], for example, requires the prescription form to recite that it will be filled generically unless the doctor signs over the line stating "dispense as written." The other signature line which must appear on the form reads "substitution permissible", and a signature on that line mandates the pharmacist to substitute a less expensive generic equivalent. Other state laws make substitution of a generic equivalent mandatory unless the physician vetoes such substitution by writing the words "dispense as written", "do not substitute", or similar terminology on the prescription form.[21]

The patient is not a stranger to the foregoing procedures since, in most instances, the patient see the prescription and carries it to the pharmacist. Moreover, the majority of prescriptions are written by the doctor in the presence of the patient at a time, and under circumstances where the patient's (and the doctor's) preference for a generic or brand name drug can be fully explored. There is no reason to believe that a patient is unaware that a generic drug may be dispensed rather than the brand name. Nor is there any reason to cause the patient any anxiety by changing the appearance of a medication.

Each of the state substitution laws also contains provisions for labeling the prescription container with information with respect to the name of the drug and the source of origin of the drug, and penalties to ensure compliance with these requirements. In New York and New Jersey, mislabeling is a crime and multiple

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20. N.Y. Education Law, Section 6810, 6815, 6816 (McKinney's Supp. 1981).

21. *See* Warner, Consumer Protection and Prescription Drugs: The Generic Substitution Laws, 67 Ky. L.J. 389 (1979) for an excellent discussion of the specific provisions of the State substitution laws and the differences between individual states.

violations of the labeling requirements can result in fines, imprisonment, and the loss of license to engage in dispensing prescription pharmaceuticals.[22] As noted in the decisions below and in the *Ives* case, these provisions are being enforced and indictments have been handed down. There is no reason to suppose that there will be widespread violation of these state laws by pharmacists. As this Court stated in *Virginia State Board of Pharmacy v. Virginia Citizens' Consumer Council, Inc.*, high professional standards, to a substantial extent, are guaranteed by the close regulation to which pharmacists are subject, and the pharmacists who are guilty of professional dereliction that actually endangers their customers will promptly lose their licenses. In any event, it is improper for a court to hold a generic drug manufacturer liable for unfair competition based upon product appearance simulation while simultaneously finding that patients associate that product appearance with the medication itself and not with its producer.

III.

The courts below disregarded the *Ives* decision and improperly applied Section 43(a) of the Lanham Act.

In *Ives*, this Court held that generic drug manufacturers are not liable for contributory infringement under Section 32 of the Lanham Act simply because they manufacture a "look-alike" drug and advertise that drug as a less expensive alternative to a brand name pharmaceutical product. It is now clear that "a finding of contributory infringement requires proof of either an intent to induce illegal substitution or continued sales to particular customers whom the manufacturer knows or should know are engaged in improper palming off."[23] The foregoing legal standard requires proof that the generic manufacturer intentionally induced the

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22. New York Education Law, Section 6816 (McKinney's 1981 Supp.).

23. This standard for determining contributory infringement is set forth in the concurring opinion of Justice White, 72 L. Ed. 2d at 618, *et seq.*, and is expressly adopted in the majority opinion, 72 L. Ed. 2d at 615, footnote 13.

pharmacists to mislabel generic drugs or, in fact, continued to supply generic drugs to pharmacists who were known to be engaged in mislabeling.[24]

This Court also stated that a rule which held generic manufacturers liable for acts of mislabeling committed by pharmacists merely because the generic manufacturers could "reasonably anticipate" illegal substitution or mislabeling would be a "watered down" and incorrect standard.[25] It adopted Justice White's concurring opinion which holds that the mere fact that some illegal substitution by some unknown pharmacists can be anticipated to some unspecified extent is insufficient to establish that a manufacturer is contributorily liable. As Justice White noted, there was no contributory infringement in *Snow Crest's* manufacture of a product identical in appearance to that of Coca-Cola in *Coca-Cola v. Snow Crest Beverages, Inc.*, 64 F. Supp. 980, 989 (D. Mass. 1946), *aff'd.*, 162 F.2d 280, *cert. denied*, 332 U.S. 809 (1947), although Judge Wyzanski recognized in *Snow Crest* that:

> "[A]ny man of common sense knows that in any line of business . . .there are some unscrupulous persons who, when it is to their financial advantage to do so, will palm off on customers a different product from that ordered by the customer." 64 F. Supp. at 988-989.

In the case below, the Third Circuit, relying on its earlier decision in *SK&F v. Premo* stated (625 F.2d at 1062):

> " . . .it has been held that it is actionable conduct under New Jersey law for a drug manufacturer to put a product in the hands of a pharmacist in a form in which the manufacturer can *reasonably anticipate* that it may be passed off as another

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24. 72 L. Ed. 2d at 615.

25. 72 L. Ed. 2d at 616, footnote 13. 27.

> product even if the manufacturer does nothing else to encourage passing off." [Emphasis added.)

That legal concept was overruled by *Ives*. Although *Ives* was decided under Section 32 of the Lanham Act, it clearly applies with equal force to the New Jersey common law rule since both are derived from the same precedent. Section 32 of the Lanham Act is a codification of the Supreme Court's decision in *Warner & Co. v. Eli Lilly & Co.*, and there is no suggestion that Congress intended to depart from that decision and other precedents in enacting Section 32 of the Lanham Act.[26] Moreover, the "reasonable anticipation" standard enunciated in *SK&F v. Premo* was expressly based on the Restatement of Torts, §§ 711 and 713, and the Restatement is expressly derived from *Warner*.

Any doubt concerning the question of whether the New Jersey rule is different is put to rest by the fact that the decision in *Warner* reversed a Third Court decision based on New Jersey common law. Moreover, unlike the facts here, that case included evidence of actual inducement of illegal substitution and not merely an allegation of "reasonable anticipation." *See Eli Lilly & Co. v. Wm. R. Warner & Co.*, 275 F. 752 (3rd Cir. 1921). In any event, the decisions of this Court in the *Sears* and *Compco* cases clearly preempt the application of state law in a manner which would enjoin the copying of appearance features. Those decisions clearly limit relief under state law to labeling or other notice provisions even in cases involving deliberate passing off.

The Third Circuit's attempt to evade the clear mandate of *Ives* with respect to Section 32 of the Lanham Act and the impact of *Sears* and *Compco* with respect to common law, by finding Bolar liable for "passing off" under Section 43(a) of the Lanham Act serves to demonstrate both the court's singlemindedness in searching for a theory to justify its decision and its lack of understanding of the law of unfair competition. In order to be guilty of a violation of Section 43(a), the party charged must be

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26. *See Ives* at 72 L. Ed. 2d at 620, footnote 2.

guilty of ". . .a false designation of origin or false description" with respect to goods or services which move in commerce. The undisputed facts of the present case establish that the only activity in which Bolar engaged was the manufacture and sale of a capsule which looked like the plaintiff's capsule. That activity cannot amount to a false description or designation of origin unless the appearance of the tablet has trademark significance, *i.e.*, designates a source of origin. Absent proof of secondary meaning, the facts of this case are indistinguishable from the facts considered by this Court more than sixty years ago in *Warner*. In that case, despite deliberate acts of passing off at the retail level, and actual inducement of those acts by the manufacturer, no relief was granted which would have required the manufacturer to change the appearance of the product because the appearance was functional and did not have source-indicating significance.

The generic substitution laws were enacted in recognition of the fact that the physician's use of the brand name as if it were the generic name and the anti-substitution laws were depriving the public of lower priced, but nevertheless, safe and effective, generic substitutes. In cases involving legal substitution—which is certainly the dominant use of generic drugs—no harm whatsoever is caused to the brand name manufacturer or the patient as a result of identical appearance. The patient gets precisely what the doctor ordered. The brand name company loses the sale only because the substitution laws provide the opportunity to buy a cheaper, equivalent product. Product appearance is irrelevant to the drug selection process.[27] In short, there is no passing off. Thus, forcing a color change serves no legitimate interest, but merely interferes with substitution by creating anxieties with respect to whether the right medication was dispensed.

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27. In *Pennwalt Corp. v. Zenith Laboratories, Inc.*, 472 F. Supp., 413, 422 (E.D. Mich. 1979), the court held drug look-alike case could not extend to dispensing doctors since they are not deceived. Precisely, the same logic applies to pharmacists and patients engaged in legal substitution.

CONCLUSION

The issues in this case affect the health and welfare of all citizens and deserve to be heard by this Court.

Respectfully submitted

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(6)

No. 84-1620

IN THE
SUPREME COURT OF THE UNITED STATES

October Term, 1984

BOLAR PHARMACEUTICAL COMPANY, INC.,

Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

On Petition For Writ of Certiorari
To The United States Court of Appeals
For The Third Circuit

BRIEF AMICUS CURIAE OF THE ILLINOIS PHARMACISTS ASSOCIATION

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No. 84-1620
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BRIEF AMICUS CURIAE OF THE ILLINOIS PHARMACISTS ASSOCIATION

INTEREST OF THE ILLINOIS PHARMACISTS ASSOCIATION

The Illinois Pharmacists Association[1] ("IPhA") is a professional society of pharmacists having a membership of over two thousand five hundred pharmacists engaged in all aspects of pharmacy practice and

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1 The administrative office of the IPhA are located at Suite 400, 222 West Adams Street, Chicago, Illinois 60606.

teaching throughout the State of Illinois.

The Third Circuit decision in this case grants a nationwide monopoly on the appearance characteristics of drug dosage forms which function to identify the drugs themselves. It authorizes failure to select and promote useful generic names for drugs. The decision of the Third Circuit will accordingly adversely affect drug product selection, pharmacy communication with patients and public health and safety in the State of Illinois.

The IPhA submits this brief in support of the Petition for Certiorari, pursuant to Rule 36.1 of the Rules of this Court, written consent of the parties being submitted herewith.

The IPhA's position is that the Third Circuit's Opinion in this case should be overturned to the extent that it affirmed a ruling based on a series of presumptions including the presumptions that Bolar acted in bad faith merely because it elected to manufacture a generic drug in publicly accustomed

colors and that Bolar intended to facilitate illegal substitution by pharmacists.[2] Since the rejection of the "reasonable anticipation" standard by this Court in Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc., 456 U.S. 844 (1982) as it applied to Section 32 of the Lanham Act, the use of the "reasonable anticipation" standard in a Section 43 Lanham Act case should also be found to be erroneous. The use of presumptions in this case is nothing more than use of the "reasonable anticipation" standard and should consequently be rejected by this Court as inconsistent with its opinion in the Inwood case.

As an affiliate of the 55,000 member American Pharmaceutical Association, the IPhA has supported the policy of the American Pharmaceutical Association to oppose the granting of monopolies in the appearance of a drug dosage form, because drug appearance identifies

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2 The IPhA certainly does not condone any illegal activity by any pharmacist and submission of this brief should in no way be construed as a step taken in support of or in order to facilitate any potential illegal activity.

the drug itself, not its source. The IPhA concurs with the official statement of the American Pharmaceutical Association to Congress opposing monopolies on drug product appearance:

> [C]reating a monopoly as to the appearance characteristics of a drug dosage form . . . would be expected to drastically reduce the number of multi-source drug products, thereby limiting the benefits of competition for patients in the 45 states [now 49] which have laws permitting pharmacists to engage in drug product selection for the benefit of their patients. This could also have a negative impact on patient compliance with prescribed drug regimens, since patients associate drug identity with drug product appearance. Furthermore . . . [granting a monopoly on drug appearance] would exacerbate the problem of drug identification in emergency situations such as accidental poisonings" [Def. Ex. 26, Trial Record, p. 837].

In 1977, recognizing that physicians prescribe by drug "brand name" when referring to the medication itself because of habit or unfamiliarity with generic names, Illinois joined the great majority of other states by enacting its drug product selection law, Illinois Revised Statutes, Chapter 111, Paragraph 4033. This statute provides that pharmacists may dispense a lower cost drug for a "brand name" prescription under specified conditions.

The overall appearance of a drug dosage form by which it is recognized and identified must be distinguished from source identification. The IPhA also strongly supports the position of the American Pharmaceutical Association that "the name, trademark, number or code" of the drug manufacturer should be used on the dosage form itself [Def. Ex. 26, Trial Record, p. 839]. In this case, the generic manufacturer Bolar prominently printed its logo and National Drug Control Identification Number twice on each capsule, and packaged its product in distinctive containers, clearly identifying itself as the manufacturer.

The opinion of the Third Circuit interferes with the valid state policy of Illinois to facilitate generic drug substitution. The availability of generic drugs promotes competition in the pharmaceutical marketplace, with the resultant effect of cost containment. The Third Circuit decision limits the pharmacist, physician and patient seeking the drug dosage form in a uniform accustomed appearance by which it is recognized, to a single, monopoly source. Requiring generic drugs to have a different physical

appearance from that by which the drug has been recognized and identified by patients and health care professionals will have a serious anticompetitive impact on the generic drug industry.

ARGUMENT

A.
THE APPEARANCE CHARACTERISTICS OF A DRUG DOSAGE FORM SERVE TO IDENTIFY THE DRUG ITSELF AND SHOULD NOT BE MONOPOLIZED.

The functionality of the accustomed appearance for drug identification was properly expressed by this Court in its approval of the District Court decision in Inwood Laboratories, Inc., et al. v. Ives Laboratories, Inc., 456 U.S. 844 (1982), as follows:

> . . . that the blue and blue-red colors were functional to patients as well as to doctors and hospitals; many elderly patients associate color with therapeutic effect; some patients co-mingle medications in a container and rely on color to differentiate one from another; colors are of some, if limited, help in identifying drugs in emergency situations; and use of the same color for brand name drugs and their generic equivalents helps avoid confusion on the part of those responsible for dispensing drugs [456 U.S. 844 at 853].

This utility of the accustomed appearance characteristics of a drug dosage form, which is unrelated to identification of the manufacturer of the drug, was confirmed in the present case by the testimony of Dr. James O'Donnell[3] [Trial Record, pp. 351-377, 422-425].

As pointed out by this Court in its landmark Kellogg Co. v. National Biscuit Co. ("Shredded Wheat") decision:

> [A] particular manufacturer can no more assert exclusive rights in a form in which the public has become accustomed to see the article and which, in the minds of the public, is primarily associated with the article rather than a particular producer, than it can in the case of a name with similar connections in the public mind [305 U.S. 111, 118].

This Court affirmed in Inwood, supra, that there can be no grant of monopoly unless the "manufacturer can show that in the minds of the public, the primary

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[3] In addition to serving as a pharmacist member of the Generic Drug Technical Advisory Council of the State of Illinois and an experienced poison control specialist of the Chicago Poison Control Center, Dr. O'Donnell also presently serves as the Vice President for Professionals Affairs of the IPhA. Dr. O'Donnell did not, however, testify on behalf of the IPhA.

significance of a product feature or terms is to identify the source of the product rather than the product itself" Id. at 851. The primary significance of the appearance of a drug dosage form is drug identity, not source.

This issue was crystallized by Chief Justice Burger in his question to the Justice Department Attorney, Mr. Ganzfried, during oral argument in the case of Inwood v. Ives, supra as to the functionality of color for drug product identification as opposed to source identification:

> **Mr. Ganzfried:** For example, if I may take one that appears before me, a question of judicial robes. If there were one company that made judicial robes and made them black, would the second company that made them have to make them green? The question is do you identify the color with the product or do you identify it with the producer; and that is the issue in this case.
>
> **Question:** Well, in common human experience what would be, in your view, the reaction to people being handed green aspirin?
>
> **Mr. Ganzfried:** They would think it was something other than aspirin [Oral Argument Transcript, February 22, 1982, p. 29].

This is in fact the reaction of patients who, knowing a generic drug is being dispensed, receive a

drug which they do not recognize. They think it is the wrong medicine. Forcing generic competitors to sell green aspirin, or another drug of unfamiliar appearance because physicians and pharmacists may be able to convince most patients that the drug may have another appearance, is like forcing a competitor to make green judicial robes because judges can be convinced that it is still a judicial robe. It can usually be done, but it is an artificial barrier to competition.

B.
A USEFUL GENERIC NAME IS REQUIRED FOR COMMUNICATION IN THE HEALTH CARE FIELD.

Brand name manufacturers have historically directed an exhaustive advertising campaign to health care professionals during the terms of their patent monopoly on a drug product. They may deemphasize the generic name, or as in the present case, fail to even provide a useful generic name. As a consequence, many physicians come to identify a drug itself by the claimed "brand name" and write prescriptions accordingly.

Congress had addressed the problem of failure to provide useful generic drug names in both the

Trademark, and the Food, Drug and Cosmetic laws. Title 15 U.S.C. § 1064(c) of the Lanham Trademark Act provides for cancellation of claimed trademarks which are "the common descriptive name of an article or substance", and Title 15 U.S.C. § 1065(4) of the Lanham Act prevents acquisition of trademark rights in "the common descriptive name of any article or substance, patented or otherwise". In order to curb drug company failure to provide and promote useful generic drug names, and to "prevent profit when generic names cannot be remembered" [Congressional Record, Def. Ex. 31, Trial Record, pp. 952, 965, 982, 987-990], in 1962, Congress required that all prescription drug advertisements have a generic name printed in type at least half as large as that used for the claimed brand name 21 U.S.C. §352(n). Despite this requirement, none of Ciba's advertising relied on by the lower courts provides a useful generic name other than "Apresazide"; even the ingredient names are up to 20 or more times smaller than the claimed brand name "Apresazide" [Pl. Ex. 8-14, 19, Trial Record, pp. 1474-1548].

The legislatures of 49 states (including Illinois) have also sought to address the problem by adopting so-called "generic drug substitution laws" which either require or allow the dispensing pharmacist to dispense a generic drug when a "brand name" is written on the prescription, unless the physician otherwise directs.

The United States Adopted Names (USAN) Council, in cooperation with the official United States Pharmacopea, National Formulary, and the Food and Drug Administration, seeks to promote the selection and utilization of non-proprietary names for drugs:

> Teaching in pharmacy and medicine requries a common designation especially for a drug that is available from several sources, and for combinations of two or more drugs. Nonproprietary names greatly facilitate communication between physicians, and most journals demand their use. State formularies and hospital formularies generally use non-proprietary names as the titles of the articles recognized. A nonproprietary name is essential to the pharmaceutical manufacturer as a means of preserving his trademark rights in his brand name for the article concerned. Finally, federal law obliges the manufacturer to use the "established" nonproprietary name in his advertising, labels and brochures. [USAN and the USP Dictionary of Drug Names. USAN 1982, 1961-1981 Cumulative List, page 6; Def. Ex. 24, Trial Record, p. 809] (emphasis supplied)

Despite this, Ciba-Geigy has provided no useful generic name for the drug in suit, other than its claimed brand name "Apresazide". Dr. O'Donnell correctly testified that a tongue-twisting listing of its ingredients "Hydralazine Hydrochloride and Hydrochlorothiazide" is too cumbersome for use [Trial Record, pp. 353-361]. Patients certainly cannot remember these names. What name is to be used on prescription labels, and in patient communications? Ciba-Geigy's counsel acknowledged during his deposition of Mr. O'Donnell that he used "generic Apresazide because it's easier than the mouthful describing the component parts" [April 21, 1982, Deposition of Ciba's own witnesses acknowledged that "Apresazide" is the common name for the drug and that physicians commonly refer to it as "Apresazide" [Trial Record, pp. 73-77, 136, 143, 147].

The Third Circuit decision frustrates the pharmaceutical and legal requirements for providing useful generic names. Any association of drug product appearance with the name "Apresazide", where there is no other useful generic name, is an improper basis for the grant of drug appearance monopoly. The trademark

laws should not reward advertising, which fails to provide and promote a useful generic name, with a monopoly on the functional appearance characteristics of a drug dosage form.

CONCLUSION

For these reasons, the Illinois Pharmacists Association respectfully urges the Court to grant Certiorari to review the Third Circuit decision.

Respectfully submitted,

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APPENDIX

IN THE
UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CIBA-GEIGY CORPORATION,

Plaintiff,

vs.

BOLAR PHARMACEUTICAL COMPANY, INC.,

Defendant.

Civil Action No. 82-0788 (HLS)

---

[1] The deposition of JAMES THOMAS O'DONNELL called by the Plaintiff for examination, taken pursuant to the Federal Rules of Civil Procedure of the United States District Courts pertaining to the taking of depositions, taken before CATHERINE M. MROZEK, a Notary Public within and for the County of Cook, State of Illinois, and a Certified Shorthand Reporter of said state, at 1725 West Harrison Street, Chicago, Illinois, on the 21st day of April, A.D. 1982, at 2:00 p.m.

[2] PRESENT:

MESSRS. KAYE, SCHOLER, FIERMAN, HAYS & HANDLER,
(425 Park Avenue
New York, New York 10022, by:
Mr. IRA SACKS,
appeared on behalf of the plaintiff;

MESSRS. FITCH, EVEN, TABIN, FLANNERY & WELSH,
(135 South LaSalle Street
Chicago, Illinois 60603), by:
MR. JOHN F. FLANNERY,
appeared on behalf of the Defendant.

REPORTED BY: CATHERINE M. MROZEK, C.S.R.

* * *

[27] Q. Are you aware of generic - and I'm saying generic Apresazide because it's easier than the [28] mouthful describing the component parts - of their plans to market a generic Apresazide?

A. Their meaning who, Reid-Provident?

Q. Reid-Provident.

A. No, I was not aware of that.

Q. Has anybody from Bolar made you aware that Reid-Provident intends to market a generic Apresazide in a green capsule.

MR. FLANNERY: No, that's assuming a fact not in evidence, Counsel.

MR. SACKS: Well, I'll be able to get that into evidence at the hearing.

* * *

No. 84-1620

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FILED
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CLERK

IN THE

Supreme Court of the United States

October Term, 1984

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Petitioner,

v.

CIBA-GEIGY CORPORATION,

Respondent.

Petition for Writ of Certiorari to the United States Court of Appeals for the Third Circuit

PETITIONER'S REPLY BRIEF

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PETITIONER'S REPLY BRIEF

Introduction

Apparently recognizing that a clear presentation of the issues supports the granting of the writ, Respondent's Brief in Opposition is an exercise in obfuscation. (See Respondent's convoluted Counterstatement of Question Presented as example-in-chief.) It is therefore necessary to be reminded of basic principles after reading Respondent's brief.

Ciba charged Bolar with "unprivileged imitation" and "passing off"[1] under Section 43(a) of the Lanham Act and New Jersey state law.

1. These are Ciba's terms for "false designation of origin" and "contributory trademark infringement".

"Unprivileged imitation" means Bolar used Ciba's alleged trademark (the capsule colors) on Bolar's capsules. To prove "unprivileged imitation" Ciba must show both that the colors of its capsules have become a trademark (have acquired secondary meaning) and are non-functional.

"Passing off" means that pharmacists illegally substitute Bolar's product for Ciba's, and that Bolar is liable for that unlawful activity. To prove "passing off" Ciba must show that Bolar intentionally induced illegal substitution by pharmacists, or continued to sell to a pharmacist who Bolar knew was engaging in illegal substitution.

Bolar requests a writ of certiorari because the courts in the Third Circuit are applying improper legal criteria to a determination of these issues, which results in a conflict between the Third Circuit and the Second Circuit in cases with indistinguishable facts. Ciba opposes the writ, contending that Bolar is merely complaining about adverse findings of fact by the trial court.

POINT I

The Courts Below Applied Improper Legal Criteria to the Determination of the "Unprivileged Imitation" Claim.

A. Secondary Meaning

The finding of secondary meaning by the courts below, which was essential to holding Bolar liable for both "unprivileged imitation" and "passing off" under Section

43(a) of the Lanham Act and New Jersey law,[2] was based not on a finding of fact but upon the application of an inappropriate legal standard. Respondent admits that the conflict between the district court in *Ives*[3] (affirmed by the Second Circuit) and the district court in this case (affirmed by the Third Circuit) is traceable solely to the legal criteria used for determining secondary meaning. That is why Respondent must defend the legal criteria applied by the New Jersey District Court as "well settled" and "correct" (Respondent's Brief, page 18).

The conflict clearly presented to this Court for review on the issue of secondary meaning is one of law, i.e., whether the district court (affirmed by the Third Circuit) applied the correct legal standard in finding that the color of Ciba's drug capsules attained trademark significance.

The issue is whether the primary significance of the color of prescription drug capsules is to identify the source of the product, rather than the product itself, in the mind of the consumer. *Kellogg Co.* v. *National Biscuit Co.*, 305 U.S. 111, 118 (1938) and *Ives*, 456 U.S. at 851, fn. 11. Ciba argues that it is proper to decide the issue by reference to

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2. The question of whether drug capsule colors have become trademarks is central to both claims made by Ciba. Obviously there is no "unprivileged imitation" of a trademark if the colors are not a trademark, and the copying of colors cannot support the "passing off" claim if they are not indications of source. (See Judge Nickerson's discussion of this question in his first *Ives* decision. *Ives Laboratories* v. *Darby Drug Co., Inc.*, 455 F. Supp. 939 at 950, fn. 3 [1978]) Therefore, Ciba's contention that alternative holdings support the Third Circuit's decision is simply wrong. If the court below erred in finding secondary meaning, neither the "unprivileged imitation" nor the "passing off" claim survives.

3. *Ives Laboratories, Inc.* v. *Darby Drug Co., Inc.*, 488 F. Supp. 394 (E.D.N.Y. 1980), rev'd. 638 F.2d 538 (2d Cir. 1981), rev'd. sub nom., *Inwood* v. *Ives*, 456 U.S. 844 (1982), aff'd. on remand, 697 F.2d 291 (2d Cir. 1982).

the extent of sales and promotion by the originator, and copying by the competitor. Bolar contends that, in the prescription drug context where advertising and promotion do not reach the consumer, and where the consumer does not choose the product sold, those criteria make no sense. Only direct evidence, such as a survey or testimony of consumers, is truly relevant and material.

Bolar's arguments as to the inappropriateness of the legal standard used in the Third Circuit to find secondary meaning are set out at pp. 18-23 of the Petition. Respondent totally fails to deal with those arguments, which cannot be logically disputed. In addition, Respondent ignores its own failure to present survey evidence (or direct evidence) of the significance of color to the consumers of Apresazide or any prescription drug product. If the correct criteria are applied, Ciba's failure to present any direct or survey evidence on the significance of capsule color to the consumer would be fatal to its claims. (See the *amicus* brief of the Generic Pharmaceutical Manufacturers Association, pp. 6-7.)

This is not an issue of fact but a substantial and significant question of law which requires corrective action by this Court, failing which the colors of brand name drugs will be held to be trademarks despite the total absence of evidence as to the significance of drug capsule (or tablet) color in the minds of the public.[4]

4. Respondent is partially correct in stating that this Court failed to finally resolve the issue in *Ives*. There the Court restated the importance of determining the significance of color in the mind of the consumer (456 U.S. at 851, n. 11) but failed to choose between the legal criteria to be applied in deciding the issue. The result of that omission is the problem now confronting the drug industry, where the Third Circuit adopts one legal principle and the Second Circuit another, causing a conflict in decisions despite identical fact patterns.

B. Functionality

The Petition does not seek to review findings of fact on the issue of functionality. As emphasized in the petition, the facts of this case, the *Ives* case and virtually all generic drug look-alike cases are the same. Only the conslusions differ.

Respondent does not seriously dispute the Petitioner's central contention that the facts of this case are virtually identical to *Ives*.[5] Respondent expressly admits in its Brief in Opposition that the result in this case differs from the result in *Ives* because the district courts in New York and New Jersey "reached different factual *conclusions* with respect to the issue (of functionality)" (p. 14) (emphasis added). It is the *conclusions* that differ, not the factual findings.

The district courts in New York and New Jersey come to different conclusions based on identical facts because they apply different legal standards to those facts. The situation is analogous to a jury trial in a negligence case where the finder of fact first decides what the facts are (e.g., was the traffic light red or green in a particular direction at the time of the accident) and then goes on to apply the law

5. Respondent's only attempt to distinguish this case from *Ives* on their facts is tucked away in the middle of footnote 15 of Respondent's Brief (p. 17). There it is claimed that a generic equivalent of Apresazide made by another company is sold in colors different from those chosen by Ciba, whereas the drug in the *Ives* case, Cyclospasmol, was hard to sell in different colors. Reliance on this petty distinction is tantamount to an admission that the cases are fundamentally indistinguishable. Moreover, the fact that a company other than Bolar choose to compete with Ciba by distinguishing its product from Ciba's should not preclude Bolar from competing by emphasizing the similarity of its product to Ciba's, and competing on the basis of a lower price. (See Petition, pp. 26-28).

given by the judge to those facts to reach a *conclusion* of fact as to the parties' negligence. If the judge makes an error in his charge, it is a mistake of law which affects the jury's ultimate factual conclusion. In the case at bar the trial judge made the same basic factual findings as the trial judge in *Ives,* e.g., color was arbitrarily chosen in the first instance by Ciba and by Ives, advertising reaches only physicians and not patients, patients suffer anxiety when receiving pills in an unexpected color, anxiety can be assuaged by informing the patient that it is the same drug, patients use drug color to follow prescription instructions and to communicate with doctors, etc. The error made by the trial judge in this case was to apply inappropriate legal criteria to those facts and thereby reach a factual conclusion of non-functionality at odds with the conclusion of the courts in the Second Circuit. Therefore, as the Petition asserted (at pp. 24-25), Bolar seeks review of the legal standards applied in the Third Circuit (summarized at the bottom of p. 25 of the Petition and discussed at pp. 26-29), not the factual findings of the trial court.

Two courts cannot consider virtually identical facts and reach opposite conclusions unless they apply different legal standards to those facts. The application of improper legal standards to the determination of whether the color of prescription drug capsules and tablets has in the mind of the consumer attained secondary meaning, and if so whether such colors are non-functional, in a controversy with such far reaching social and economic implications, is an appropriate subject for review by this Court.

POINT II

"Passing Off": The Continued Use of the Reasonable Anticipation Standard Should Be Reviewed.

Beneath the confusing rhetoric, Respondent claims that the use of the "reasonable anticipation" standard for finding Bolar vicariously responsible for presumed (not proven) illegal substitution by pharmacists, is harmless because the trial judges' finding of "intent" is sufficient to support liability under the proper standard set forth in *Ives*. 456 U.S. at 854 (fn. 13), 860 and 861. Secondly, Respondent argues that the "reasonable anticipation" standard survives *Ives* if it is applied to Section 43(a) claims or claims brought under state laws of unfair competition.

The trial court's finding of "intent" by Bolar to facilitate "passing off" is an attempt to shield the decision from review. It is significant that Ciba's counsel actually drafted the trial court's opinion (see App. 32, fn. 10), and obviously had in mind the avoidance of reversal on appeal. Despite counsel's admiration for his own cross-examination of Bolar's president (see Respondent's Brief, p. 22), there is not a scintilla of evidence cited to support a finding that Bolar intended pharmacists to use its product illegally. Bolar's president testified that he thought use of Ciba's colors would increase the sale of the Bolar product. There is nothing wrong with that. As the Third Circuit majority noted, "Bolar's argument that copying of APRESAZIDE's trade dress is in the public interest is not necessarily a frivolous assertion. . . ." (App. 78, fn. 5) The testimony of Bolar's president, undistorted by Respondent, was simply that Bolar wanted to increase sales by selling a more useful (i.e., functional) product. That necessitated use of the

colors Bolar considered functional. To twist his statement into support for a finding of intent to induce illegal substitution is nothing less than intellectual dishonesty.

However, Bolar need not "quibble" about the lack of support for the trial judge's finding of intent to pass off. It is clear from *Ives* that more than intent is needed to support a finding of contributory trademark infringement. (See Judge Giles' analysis at App. 96-97.) In this case there is nothing except copying on which to base a finding of contributory infringement. There is no other act by Bolar in the record. Thus, the mischief of the "reasonable anticipation" standard is that it permits a finding of vicarious liability (contributory trademark infringement) in the absence of evidence that Bolar did anything to *induce* illegal substitution. The continued use of the "reasonable anticipation" standard is far from harmless—applying that incorrect standard is the only way Bolar can be held liable for "passing off" based on nothing more than the act of copying the Apresazide colors. The "reasonable anticipation" standard was rejected in *Ives* to avoid the possibility of finding a manufacturer vicariously liable for a pharmacist's wrongful acts unless the manufacturer *did something* to induce those acts. The courts below seek to avoid that holding in *Ives* by continued use of the "reasonable anticipation" standard. Unless this case is reviewed, generic drug manufacturers will be vicariously liable for the acts of pharmacists although the manufacturers do nothing more than copy the brand name colors. That is the result this Court in *Ives* attempted to prevent.

The Respondent's arguments that the "reasonable anticipation" standard survives in Section 43(a) claims because *Ives* dealt with a Section 32 claim has already been

dealt with in the Petition. (See p. 14.) Respondent has failed to answer the point made by Judge Giles quoted in the Petition, and it need not be repeated here.

Respondent argues that the "reasonable anticipation" standard survives in state law claims. This ignores Respondent's concession that the state law claims are identical to the Section 43(a) claims (Respondent's Brief, p. 3, fn. 4). Moreover, state law cannot prohibit copying articles in commerce unprotected by trademark, patent or copyright. *Sears, Roebuck & Co.* v. *Stiffel Co.*, 376 U.S. 225 (1964), and *Compco Corp.* v. *Day-Brite Lighting, Inc.*, 376 U.S. 234 (1964) Respondent's assertion that the Second Circuit in *Ives* held that *Sears* and *Compco* permit the prohibition of copying under state laws of unfair competition (Respondent's Brief, p. 24, fn. 21) is a misstatement of Judge Friendly's opinion. The Second Circuit said that *Sears* and *Compco* did preclude such relief under state laws of unfair competition, but did not necessarily preclude relief under the Lanham Act. *Ives Laboratories, Inc.* v. *Darby Drug Co., Inc.*, 601 F.2d 631, 642 (2d Cir. 1979) If state laws can prohibit copying of an unpatented, unregistered, uncopyrighted feature of an article in commerce, such as drug capsule colors in the case at bar, then *Sears* and *Compco* are totally meaningless and should be expressly repudiated.

As the *amicus* briefs point out, the New Jersey decisions have radically altered a long standing industry practice of selling generic drugs in the same colored capsules and tablets as their brand name counterparts. It is particularly important to review a holding of liability based on New Jersey state law which is in conflict with this Court's interpretation of the Lanham Act, where the effect of the

lower court's decision is to reverse an industry practice and establish a national prohibition against selling generic drugs in the only colors the consuming public has come to associate with their respective ingredients and their therapeutic effect.

Conclusion

The sole purpose of this Reply Brief is to answer the points raised by Respondent in its Brief in Opposition. It is not the Petitioner's intention in this Reply Brief to repeat or to summarize the reasons for the allowance of the writ. Those reasons are stated fully in the Petition, and it is respectfully requested that the Court refer to the Petition, and not to this Reply Brief, for the complete statement of Petitioner's position on the issues presented by this case.

For the reasons stated in the Petition, in the *amicus* briefs, in Judge Giles' dissent, in Judge Nickerson's opinions in *Ives* and in this Court's opinions in *Ives* and *Kellogg,* Petitioner requests the allowance of a writ of certiorari.

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Respectfully submitted,

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